Agenda Item XI

LEGISLATION AND REGULATION COMMITTEE REPORT

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member Ramón Castellblanch, Public Member Deborah Veale, RPh Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

PART II - LEGISLATION

a. BOARD SPONSORED LEGISLATION FOR 2012

ATTACHMENT 1

SB 1575 (Senate Committee on Business, Professions and Economic Development, Price, Chair)

Last Amend: April 16, 2012

Location: Senate Appropriations

Status: No hearing set as of 4/24/12

Each year the Senate Committee on Business, Professions and Economic Development sponsors omnibus measures.

SB 1575 contains two omnibus proposals sponsored by the board:

- Section 4209 of the Business and Professions Code would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants. This language was approved by the board in October 2011.
- Section 4300.1 of the Business and Professions Code would ensure the board can put discipline on record even if the license is cancelled. This language was approved by the board in January 2012

In addition, SB 1575 contains a department-sponsored proposal to add Section 144.5 to the Business and Professions Code to authorize a board to request – and require a local or state agency to provide – certified records, such as arrests, convictions, and other documents required to complete an applicant or licensee investigation.

The bill was introduced on March 12, 2012, containing multiple omnibus provisions for various boards, bureaus and entities and, on April 16, was amended to include the boards sponsored provisions. The bill passed out of Senate BP&ED on consent on April 23, and was referred to Senate Appropriations. A copy of SB 1575 and an analysis is provided in **Attachment 1.**

COMMITTEE RECOMMENDATION: SUPPORT

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

ATTACHMENT 2

Sunset Review and Legislative Oversight

1. SB 1237 (Price) – Sunset Extension to 2017

Last Amend: April 16, 2012

Location: Senate Appropriations

Summary: In November 2011, the Board provided its "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board's public website. The board last underwent sunset review in 2002. Board President Stan Weisser and Executive Officer Giny Herold testified before the Senate Committee on Business, Professions and Economic Development on March 19, 2012, and responded to the committee's questions and comments.

The committee passed the measure (on consent) on April 23, 2012, and the bill was referred to Appropriations.

COMMITTEE RECOMMENDATION: Affirm Board SUPPORT

Regulation of Dangerous Drugs and Devices

2. SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program

Last Amend: March 29, 2012 (Introduced Feb. 23, 2012)

Location: SEN Com. on Business, Professions and Economic Development

Hearing: May 7, 2012 in SEN BP&ED

Summary: Under current law a county may establish a repository and distribution program under which a pharmacy may distribute donated/surplus medications, as defined, to persons in need of financial assistance. Currently, skilled nursing facilities, manufacturers, or pharmacy wholesalers may donate medications to a program. Under these programs, donated drugs must be either (1) dispensed to an eligible patient,

(2) destroyed as pharmaceutical waste, or (3) returned to a reverse distributor. With certain exceptions, those who donate medications to these programs are not subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program. SB 1329 would expand repository and drug distribution programs by also allowing a county health officer to establish a program, and would expand the pool of defined entities that can donate drugs to the program. SB 1329 would also allow donated drugs to be transferred from one program to another. The bill would require certain information to be reported to the county, and would allow the board to request this information. The bill specifies entities, including the Board of Pharmacy, that may prohibit a pharmacy or clinic from participating in a program, as specified.

Senator Simitian addressed the Legislation and Regulation Committee on April 24, 2012, and asked for the board's support of this legislation. He stated that SB 1329 is designed to make these programs more effective, and allow more people to donate drugs. Senator Simitian said he shares the board's concern to maintain the integrity of the drug supply chain, and that he would be happy to work with the board to address its concerns.

COMMITTEE RECOMMENDATION: Support if Amended

3. SB 419 (Simitian) Solid Waste: Home Generated Sharps

Introduced: February 16, 2011

Location: In ASM. Ordered to Inactive File on Request of Assembly Member Allen

(1/9/12)

Summary: Existing law permits hospitals and other entities to accept for disposal homegenerated sharps, as specified. Currently a pharmaceutical manufacturer that sells or distributes a medication in California that is self-injected, as specified, is required to submit to the Department of Resource Recovery and Recycling a plan that describes what actions, if any, the manufacturer supports for the safe management of sharps. This bill would require that the manufacturers provide their reports to DRRR electronically and also make them readily accessible on the manufacturers websites. The measure is currently on the Inactive File, and the committee did not recommend a position on the measure.

4. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply

Last Amend: April 16, 2012

Location: Senate Appropriations

Status: On April 23, the bill passed out of the SEN Committee on Business

Professions and Economic Development. Do-pass to Appropriations (Fiscal: yes)

This measure would specify conditions under which a pharmacist may dispense a 90-day supply of a dangerous drug, as specified, without first receiving authorization from the prescriber. The board's regulation at 16 CCR 1716 precludes a pharmacist from deviating from the requirements of a prescription, except as specified.

COMMITTEE RECOMMENDATION: Support

5. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Board Position: Oppose (Ver. Jan. 17, 2012)

Last Amend: January 17, 2012

Location: Senate Third Reading File (4/26/12)

Summary: AB 389 seeks to establish the Standards for Service for Providers of Blood Clotting Products for Home Use Act by imposing specified requirements on providers of blood clotting products for home use. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. The January 17, 2012, version of the bill removed references to home nursing services. The board reaffirmed its position of Oppose at the January 2012 Board Meeting. The committee did not discuss the measure, as nothing has changed with the bill since the board established a position.

6. AB 1442 (Wieckowski) Common Carriers to Transport Pharmaceutical Waste

Last Amend: March 27, 2012

Location: In Assembly. Referred to Appropriations Suspense File (4/18/12)

Summary: AB 1442 amends the Medical Waste Management Act (under the jurisdiction of the CDPH) to define, for purposes of the act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The measure excludes from the definition of "pharmaceutical waste" drugs that must be returned via a reverse distributor pursuant to section 4040.5 of the Business and Professions Code. As amended, supplies of dangerous drugs would be able to be transported by common carriers.

The Legislation and Regulation Committee discussed the bill at its recent meeting and discussed the need for controls in the movement of the drugs that are picked up and shipped.

COMMITTEE RECOMMENDATION: Oppose Unless Amended

7. AB 2369 (Valadao) Prisoners: Pharmacy Services

Introduced: February 24, 2012

Location: ASM Business, Professions and Consumer Protection

Status: Hearing set for April 24, 2012

Summary: Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for facilities under the jurisdiction of the DCR that is cost effective and efficient, and that may incorporate a requirement for the use of generic medications, when available, with certain exceptions. AB 2369 would instead *require* the use of generic medications, when available, with certain exceptions. AB 2369 does not seek to modify existing Pharmacy Law.

AB 2369 was heard in the Assembly Committee on Business, Professions and Consumer Protection on April 17th and failed passage. Reconsideration was granted, and the bill is again set for hearing for April 24, 2012. The committee did not recommend a position on this measure.

8. AB 2348 (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics

Last Amend: March 29, 2012 (Introduced on 2/24/12)

Location: ASM Rules

Status: Passed out of ASM Business and Professions and was referred to

ASM Rules

Summary: The Nursing Practice Act authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse- midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

The committee discussed AB 2348 but did not recommend a position on the measure. Staff is awaiting a response from the Board of Registered Nursing and will provide any updated information during the meeting.

COMMITTEE RECOMMENDATION: WATCH

Licensing and Pharmacy Operations

9. SB 1095 (Rubio) Pharmacy: Surgical Clinics

Introduced: February 16, 2012

Location: Senate Appropriations (Fiscal: yes)
Status: Set for Hearing April 30, 2012

Summary: SB 1095 would expand the definition of a clinic in Section 4190 to include not only surgical clinics licensed by the CDPH under H&SC Section 1204, but also to accredited outpatient settings and to Medicare certified ambulatory surgical centers, as specified. SB 1095 would provide that board licensure is optional, and that the board is authorized to inspect only those clinics which are licensed by the board. A clinic licensed by the board would be able to comingle the drug stock of the clinic and would authorize the clinic to purchase drugs at wholesale. SB 1095 would provide that nothing in the article shall preclude a physician and surgeon from dispensing dangerous drugs as provided in B&PC Section 4170.

The committee discussed SB 1095 at its meeting held April 24, 2012. It was the consensus of the committee that staff would work with the author on a solution.

COMMITTEE RECOMMENDATION: Support if Amended

10. SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies

Introduced: February 24, 2012

Location: Senate Appropriations (Fiscal: yes)

Summary: This bill would exempt from clinical laboratory licensing requirements and regulations, specified tests performed by a pharmacist in a community pharmacy. These are the same tests that pharmacists are currently authorized to perform pursuant to Section 4052.4 in specified clinic settings. Tests deemed CLIA Waived are those tests approved by the FDA as over-the-counter tests. Proponents believe this measure will result in greater access to safe, simple and economic tests that will play a crucial role in improving drug therapy, and improve patient health.

The committee spoke in support of the measure.

COMMITTEE RECOMMENDATION: Support

11. AB 377 (Solorio) Hospital Central Fill Pharmacies

Last Amend: April 14, 2011

Board Position: Support if Amended (Ver. 4/14/11)

Location: Senate Appropriations

Status: No hearing date set as of 4/16/12

Summary: AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment, and staff has been advised that the bill will be moving forward in 2012.

The committee noted that the measure has not changed since the board established its position in April 2011. During the meeting the committee was advised by the sponsor that amendments will be made that should address the board's concern.

COMMITTEE RECOMMEDATION: No Change

12. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners

Last Amend: March 27, 2012

Location: Assembly Third Reading File (4/26/12)

Summary: This measure seeks to codify into state law existing federal law (the Patient Protection and Affordable Care Act). This bill would specify that a healthcare professional employed by a tribal health program is exempt from state licensure if that health professional holds a license from another state. The committee recommend a position on this bill.

13. AB 1904 (Block) Military Spouses: Temporary License

Introduced: February 22, 2012

Location: Assembly Appropriations Suspense File

Summary: This measure would permit the board to issue a temporary permit to an applicant that submits an application, fees, and fingerprints and satisfies specified requirements including proof of licensure in good standing in another state with similar requirements. It would require the board to expedite the processing for the purpose of issuing a temporary license, would specify the term that a temporary license would be valid, and authorize the board to promulgate regulations to implement the provisions.

Staff anticipates that this may impact two primary license types: Pharmacist, and Pharmacy Technician.

The committee spoke in support of the measure, noting that the bill would require that a new license type be established, and that the board may need to specify in regulation how these licenses would be handled.

COMMITTEE RECOMMENDATION: Support

Other

14. SB 1185 (Price) Centralized Intelligence Partnership Act

Last Amend: April 9, 2012

Location: Referred to Senate Appropriations Committee

Summary: This bill would create a Centralized Intelligence Partnership ("partnership") consisting of various agencies, including the Department of Consumer Affairs, that would be charged with combating the underground economy, and would specify the general scope of the committee's process. This bill would allow information to be shared between committee participants and would provide that shared information would retain its confidential status as authorized by law.

The committee noted that the bill was scheduled for hearing in Senate Committee on Governmental Organizations on April 24, and determined that staff will bring back to the committee or the board issues that may need to be addressed. The committee did not recommend a position on this measure.

15. SB 1195 (Price) Pharmacy Benefits: Audits

Last Amend: March 26, 2012

Location: Senate Committee on Health

Status: Do Pass from Senate Health. Re-referred to Senate Rules

Summary: SB 1195 would follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers (PBMs). Pharmacy Benefit Managers are currently not regulated. Although the board does not have jurisdiction over the auditing of claims for reimbursement, board staff receive complaints on a somewhat routine basis from licensees complaining about the perceived unjust auditing practice of an auditing company receiving payment based on the number of claims rejected. This proposal would appear to address this issue.

The committee did not recommend a position on SB 1195, noting that the bill addresses issues between pharmacies and payors – which is not an area in which the board exercises jurisdiction.

16. SB 1250 (Alguist) Medical Records: Confidentiality

Introduced: February 23, 2012

Location: Senate Judiciary Committee hearing scheduled for May 8, 2012

Summary: The Confidentiality of Medical Information Act specifies the confidentiality of information maintained in medical records by health care providers, health coverage plans, pharmaceutical companies and others. Section 56.35 of the Civil Code also provides for monetary penalties for individuals and entities that violate the act. This will would specify that in addition to other legal remedies, a defendant may be required to pay for credit monitoring and reporting services for one year from the unauthorized release of medical information.

The committee did not recommend a position on this measure.

17. AB 2342 (Torres) Controlled Substances

Staff has been advised that AB 2342 in its current form will not be moving forward this year. No staff analysis is provided, and the committee did not make a recommendation on this measure.

18. AB 1733 (Logue) Telehealth

Last Amend: April 16, 2012

Location: Assembly Committee on Health Status: Hearing Scheduled April 24, 2012

Summary: AB 1733 impacts the coverage of telehealth benefits for health care service plans and programs. This bill would specify that the mandated in-person contact prohibition would also apply to health care service plan contracts with the Department of Health Care Services for services provided by the Medi-Cal program, other publicly supported programs, as well as to organizations implementing the California Program of All-Inclusive Care for the Elderly (PACE).

The committee did not make a recommendation on this measure.

Additional Legislation Impacting the Board or its Regulatory Jurisdiction

19. AB 2570 (Hill) Licensees: Settlement Agreements

Introduced: February 24, 2012

Location: Assembly Committee on Business Professions and Consumer Protection

Status: Hearing set for April 24, 2012

Summary: This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board.

The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

Staff will provide an analysis to the board at the May 2012 board meeting.

Attachment 1

Introduced by Committee on Business, Professions and Economic Development (Senators Price (Chair), Corbett, Correa, Emmerson, Hernandez, Negrete McLeod, Strickland, Vargas, and Wyland)

March 12, 2012

An act to amend Sections *1934*, *1950.5*, 2021, 2064, 2184, 2220, 2424, 2516, 2518, 2904.5, 3057.5, 3742, 3750, 3750.5, *4209*, *4600*, *4601*, *4603.7*, *4612*, 4980.04, 4980.34, 4980.398, 4980.399, *4980.43*, 4980.44, 4980.48, 4980.78, 4980.80, 4984.4, 4989.16, 4989.42, 4992.07, 4992.09, 4996.6, 4999.22, 4999.32, *4999.46*, 4999.57, 4999.58, 4999.59, *4999.62*, *4999.76*, 4999.90, 4999.106, and 4999.120 of, to add Section *Sections* 144.5, *1902.2*, *1942*, *1958.1*, *and 4300.1* to *repeal Section 1909.5 of*, and to repeal and amend Section 4999.45 of, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 1575, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

(1) Under existing law, specified professions and vocations boards are required to require an applicant to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would authorize such a board to request, and would require a local or state agency to provide, certified records of, among other things, all arrests and convictions needed by a board to complete an SB 1575 -2-

applicant or licensee investigation. By imposing additional duties on local agencies, the bill would impose a state-mandated local program.

(2) Existing law, the Dental Practice Act, provides for the licensure and regulation of the practice of dentistry by the Dental Board of California within the Department of Consumer Affairs. Existing law establishes the Dental Hygiene Committee of California under the jurisdiction of the board and provides for the licensure and regulation of the practice of dental hygienists by the committee.

This bill would require dental hygienists, upon initial licensure and renewal, to report their employment status to the committee and would require that information to be posted on the committee's Internet Web site. This bill would also require an approval dental hygiene education program to register extramural dental facilities, as defined, with the committee.

Existing law provides that a dental hygienist may have his or her license suspended or revoked by the board for committing acts of unprofessional conduct, as defined.

This bill would include within the definition of unprofessional conduct the aiding or abetting of the unlicensed or unlawful practice of dental hygiene and knowingly failing to follow infection control guidelines, as specified.

Existing law authorizes the committee to deny an application for licensure or to revoke or suspend a license for specified reasons.

This bill would require the committee to deny a license or renewal of a license to any person who is required by law to register as a sex offender.

(2)

(3) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under existing law, the board issues a physician and surgeon's certificate to a licensed physician and surgeon. Existing law provides for the licensure and regulation of the practice of podiatric medicine by the California Board of Podiatric Medicine within the Medical Board of California.

Existing law requires the Medical Board of California and the California Board of Podiatric Medicine to provide written notification by certified mail to any physician and surgeon or podiatrist who does not renew his or her license within 60 days of expiration.

This bill would require the Medical Board of California and the California Board of Podiatric Medicine to provide that written

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notification either by certified mail or by electronic mail if requested by the licensee. The bill would require the Medical Board of California to annually send an electronic notice to all licensees and applicants requesting confirmation that his or her electronic mail address is current.

Existing law authorizes the Medical Board of California to take action against all persons guilty of violating the Medical Practice Act. Existing law requires the Medical Board of California to enforce and administer various disciplinary provisions as to physician and surgeon certificate holders.

This bill would specify that those certificate holders include those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders.

(3)

(4) Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of the practice of licensed midwifery by the Medical Board of California. A violation of the act is a crime. Under existing law, these licenses are subject to biennial renewal that includes the payment of a specified fee and the completion of specified continuing education.

This bill would exempt a licensee from those renewal requirements if the licensee has applied to the board and has been issued a retired status license. The bill would prohibit the holder of a retired status license from engaging in the practice of midwifery. Because a violation of that prohibition would constitute a crime, the bill would impose a state-mandated local program.

(4)

(5) Existing law, the Psychology Licensing Law, provides for the licensure and regulation of psychologists by the Board of Psychology. Existing law provides that a licensed psychologist is a health care practitioner for purposes of specified telehealth provisions that concern the delivery of health care via information and communication technologies.

This bill would instead provide that a licensed psychologist is a health care provider subject to those telehealth provisions.

(5)

(6) Existing law, the Respiratory Care Practice Act, provides for the licensure and regulation of the practice of respiratory care by the Respiratory Care Board of California.

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Under existing law, during the period of any clinical training, a student respiratory care practitioner is required to be under the direct supervision, as defined, of a person holding a valid and current license.

This bill would require such a student to be under the direct supervision of a person with a valid, current, and unrestricted license.

Existing law authorizes the board to order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license for specified causes including a pattern of substandard care.

This bill would expand that provision to also include negligence in the licensee's practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

Existing law authorizes the board to deny, suspend, place on probation, or revoke the license of any applicant or licenseholder who has obtained, possessed, used, or administered to himself or herself, or furnished or administered to another, any controlled substances or dangerous drug, except as directed by a specified health care provider.

This bill would also make illegally possessing any associated paraphernalia a ground for the denial, suspension, placing on probation, or revocation of a license.

(7) Existing law, the Pharmacy Law, provides for the California State Board of Pharmacy within the Department of Consumer Affairs, to license and regulate the practice of pharmacy.

Existing law authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct, as specified.

This bill would modify the practice requirements applicable to intern pharmacists. The bill would also provide that the board continues to have jurisdiction in a disciplinary action against a licensee, even if the license is expired, cancelled, forfeited, suspended, revoked, placed on retired status, or voluntarily surrendered.

(8) Existing law provides for the voluntary certification of massage practitioners and massage therapists by the California Massage Therapy Council. Existing law provides specified educational and other requirements for an applicant to obtain a massage therapy certificate.

This bill would set minimum educational hour and course requirements for an applicant to qualify to receive a massage therapy certificate. The bill would also define "operator of a massage business" for purposes of these provisions.

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Existing law requires a certificate holder to display the certificate at his or her place of business.

This bill would require the certificate holder to display the original certificate at his or her place of business and to have the identification card, issued by the council, with him or her whenever providing massage therapy services. This bill would also require a massage therapist to surrender his or her identification card when his or her certificate is suspended or revoked.

Existing law authorizes a city, county, or city and county to require background checks of certain uncertified owners or operators of massage therapy establishments.

This bill would authorize that background check to include a criminal background check, including submission of fingerprints and employment history for the 10 preceding years.

Existing law authorizes a city, county, or city and county to charge certain massage businesses or establishments a business licensing fee, provided that the fee charged is no different than what is uniformly applied to other individuals and businesses providing professional services, as specified.

The bill would require that the licensing fee charged to massage businesses or establishments be no higher than those charged to other professions. The bill would also prohibit a city, county, or city and county from requesting information from those businesses or establishments that is different from that requested of others providing professional services.

(6)

(9) Under existing law, the Board of Behavioral Sciences is responsible for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors.

Under existing law, a license that is not renewed within 3 years after its expiration may not be renewed. However, the former licensee is authorized to apply for and obtain a new license if certain requirements are met, including, but not limited to, passing one or more current licensing examinations, as specified and submitting certain fees.

This bill would additionally require a former licensee to comply with the fingerprint requirements established by board regulation or as directed by the board. *The bill would make other technical and clarifying changes*.

(A)

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(10) Existing law, the Marriage and Family Therapist Act, with respect to applicants for licensure or registration by reciprocity or for those applicants who obtained education or experience outside of California that apply on and after January 1, 2014, existing law provides that education is substantially equivalent if certain requirements are met, including the completion of a course in California law and professional ethics.

This bill would require that course to be 18 hours in length.

For persons who apply for licensure between January 1, 2010, and December 31, 2013, existing law authorizes the board to issue a license to a person who holds a valid license from another state if certain requirements are met, including the completion of specified coursework or training. Existing law provides that an applicant who completed a specified course in law and professional ethics is required to complete an 18-hour course in California law and professional ethics.

This bill would instead specify that an 18-hour course in California law and professional ethics is only required if the above specified course in law and professional ethics does not meet certain requirements. *The bill would make other technical changes to those provisions.*

The bill would rename the act as the Licensed Marriage and Family Therapist Act.

(B)

(11) Existing law, the Licensed Professional Clinical Counselor Act, provides for the licensure and regulation of the practice of professional clinical counseling by the Board of Behavioral Sciences.

Under existing law, to qualify for registration, an intern applicant is required to meet certain qualifications. With respect to applicants for registration who began graduate study before August 1, 2012, and complete study on or before December 31, 2018, an applicant is required to complete a minimum of 18 contact hours of instruction in California law and professional ethics prior to registration as an intern.

This bill would describe the content of that instruction for professional clinical counselors.

Existing law authorizes the board to refuse to issue any registration or license, or to suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct that includes, but is not limited to, the conviction of more than one misdemeanor or any felony involving the use, consumption, or

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self-administration of any of specified substances, or any combination thereof.

This bill would delete the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof, from the list of what constitutes professional conduct. The bill would make it unprofessional conduct to willfully violate specified provisions governing patient access to health care records.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 144.5 is added to the Business and 2 Professions Code, to read:
- 3 144.5. Notwithstanding any other provision of law, a board
- 4 described in Section 144 may request a local or state agency to
- 5 provide certified records of all arrests and convictions, certified
- 6 records regarding probation, and any and all other related
- 7 documentation needed to complete an applicant or licensee
- 8 investigation. The local or state agency shall provide those records
- 9 to the board upon receipt of such a request.
- 10 SEC. 2. Section 1902.2 is added to the Business and Professions
- 11 Code, to read:

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1902.2. (a) A licensee shall report, upon his or her initial licensure and any subsequent application for renewal or inactive license, the practice or employment status of the licensee, designated as one of the following:

- (1) Full-time practice or employment in a dental or dental hygiene practice of 32 hours per week or more in California.
- (2) Full-time practice or employment in a dental or dental hygiene practice of 32 hours or more outside of California.
- (3) Part-time practice or employment in a dental or dental hygiene practice for less than 32 hours per week in California.
- (4) Part-time practice or employment in a dental or dental hygiene practice for less than 32 hours per week outside of California.
- (5) Dental hygiene administrative employment that does not include direct patient care, as may be further defined by the committee.
 - (6) Retired.
- (7) Other practice or employment status, as may be further defined by the committee.
- (b) Information collected pursuant to subdivision (a) shall be posted on the Internet Web site of the committee.
- (c) (1) A licensee may report on his or her application for renewal, and the committee, as appropriate, shall collect, information regarding the licensee's cultural background and foreign language proficiency.
- (2) Information collected pursuant to this subdivision shall be aggregated on an annual basis, based on categories utilized by the committee in the collection of the data, into both statewide totals and ZIP Code of primary practice or employment location totals.
- (3) Aggregated information under this subdivision shall be compiled annually, and reported on the Internet Web site of the committee as appropriate, on or before July 1 of each year.
- (d) It is the intent of the Legislature to utilize moneys in the State Dental Hygiene Fund to pay any cost incurred by the committee in implementing this section.
- 37 SEC. 3. Section 1909.5 of the Business and Professions Code is repealed.
 - 1909.5. Courses of instruction for direct supervision duties added to the scope of practice of dental hygiene on or after July

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1 1, 2009, shall be submitted by the committee for approval by the dental board.

- SEC. 4. Section 1934 of the Business and Professions Code is amended to read:
- 1934. A licensee who changes his or her *physical* address of record *or e-mail address* shall notify the committee within 30 days of the change. A licensee who changes his or her legal name shall provide the committee with documentation of the change within 10 days.
- 10 SEC. 5. Section 1942 is added to the Business and Professions 11 Code, to read:
 - 1942. (a) As used in this section "extramural dental facility" means any clinical facility employed by an approved dental hygiene educational program for instruction in dental hygiene that exists outside or beyond the walls, boundaries, or precincts of the primary campus of the approved program and in which dental hygiene services are rendered.
 - (b) An approved dental hygiene educational program shall register extramural dental facilities with the committee. The registration shall be accompanied by information supplied by the dental hygiene program pertaining to faculty supervision, scope of treatment to be rendered, name and location of the facility, date operation will commence, discipline of which such instruction is a part, and a brief description of the equipment and facilities available. That information shall be supplemented by a copy of the agreement between the approved dental hygiene educational program or parent university and the affiliated institution establishing the contractual relationship. Any change in the information provided to the committee shall be communicated to the committee.
 - SEC. 6. Section 1950.5 of the Business and Professions Code is amended to read:
 - 1950.5. Unprofessional conduct by a person licensed under this article is defined as, but is not limited to, any one of the following:
 - (a) The obtaining of any fee by fraud or misrepresentation.
 - (b) The aiding or abetting of any unlicensed person to practice dentistry *or dental hygiene*.
- 39 (c) The aiding or abetting of a licensed person to practice 40 dentistry *or dental hygiene* unlawfully.

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 (d) The committing of any act or acts of sexual abuse, misconduct, or relations with a patient that are substantially related to the practice of dental hygiene.

- (e) The use of any false, assumed, or fictitious name, either as an individual, firm, corporation, or otherwise, or any name other than the name under which he or she is licensed to practice, in advertising or in any other manner indicating that he or she is practicing or will practice dentistry, except that name as is specified in a valid permit issued pursuant to Section—1701.5 1962.
- (f) The practice of accepting or receiving any commission or the rebating in any form or manner of fees for professional services, radiograms radiographs, prescriptions, or other services or articles supplied to patients.
- (g) The making use by the licensee or any agent of the licensee of any advertising statements of a character tending to deceive or mislead the public.
- (h) The advertising of either professional superiority or the advertising of performance of professional services in a superior manner. This subdivision shall not prohibit advertising permitted by subdivision (h) of Section 651.
 - (i) The employing or the making use of solicitors.
 - (j) Advertising in violation of Section 651.
- (k) Advertising to guarantee any dental hygiene service, or to perform any dental hygiene procedure painlessly. This subdivision shall not prohibit advertising permitted by Section 651.
 - (l) The violation of any of the provisions of this division.
- (m) The permitting of any person to operate dental radiographic equipment who has not met the requirements—of Section 1656 to do so, as determined by the committee.
- (n) The clearly excessive administering of drugs or treatment, or the clearly excessive use of treatment procedures, or the clearly excessive use of treatment facilities, as determined by the customary practice and standards of the dental hygiene profession.

Any person who violates this subdivision is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) or more than six hundred dollars (\$600), or by imprisonment for a term of not less than 60 days or more than 180 days, or by both a fine and imprisonment.

(o) The use of threats or harassment against any patient or licensee for providing evidence in any possible or actual

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disciplinary action, or other legal action; or the discharge of an employee primarily based on the employee's attempt to comply with the provisions of this chapter or to aid in the compliance.

- (p) Suspension or revocation of a license issued, or discipline imposed, by another state or territory on grounds that would be the basis of discipline in this state.
 - (q) The alteration of a patient's record with intent to deceive.
- (r) Unsanitary or unsafe office conditions, as determined by the customary practice and standards of the dental hygiene profession.
- (s) The abandonment of the patient by the licensee, without written notice to the patient that treatment is to be discontinued and before the patient has ample opportunity to secure the services of another registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions and provided the health of the patient is not jeopardized.
- (t) The willful misrepresentation of facts relating to a disciplinary action to the patients of a disciplined licensee.
- (u) Use of fraud in the procurement of any license issued pursuant to this article.
- (v) Any action or conduct that would have warranted the denial of the license.
- (w) The aiding or abetting of a registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions to practice dental hygiene in a negligent or incompetent manner.
- (x) The failure to report to the committee in writing within seven days any of the following: (1) the death of his or her patient during the performance of any dental hygiene procedure; (2) the discovery of the death of a patient whose death is related to a dental hygiene procedure performed by him or her; or (3) except for a scheduled hospitalization, the removal to a hospital or emergency center for medical treatment for a period exceeding 24 hours of any patient as a result of dental or dental hygiene treatment. Upon receipt of a report pursuant to this subdivision, the committee may conduct an inspection of the dental hygiene practice office if the committee finds that it is necessary.
- (y) A registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions shall report to the committee all deaths occurring in his or her practice with a copy sent to the dental board if the death

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occurred while working as an employee in a dental office. A dentist 2 shall report to the dental board all deaths occurring in his or her 3 practice with a copy sent to the committee if the death was the 4 result of treatment by a registered dental hygienist, registered dental 5 hygienist in alternative practice, or registered dental hygienist in extended functions. 6

(z) Except for good cause, the knowing failure to protect patients 8 by failing to follow infection control guidelines of the committee, thereby risking transmission of infectious diseases from dental assistant, registered dental assistant, registered dental hygienist, 10 registered dental hygienist in alternative practice, or registered dental hygienist in extended functions to patient, from patient to 12 patient, and from patient to dental assistant, registered dental 13 14 assistant, registered dental hygienist, registered dental hygienist 15 in alternative practice, or registered dental hygienist in extended functions. In administering this subdivision, the committee shall 16 17 consider referencing the standards, regulations, and guidelines of the State Department of Public Health developed pursuant to 18 19 Section 1250.11 of the Health and Safety Code, and the standards, 20 guidelines, and regulations pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing 22 with Section 6300) of Division 5 of the Labor Code) for preventing 23 the transmission of HIV, hepatitis B, and other pathogens in health care settings. The committee shall review infection control 24 25 guidelines, if necessary, on an annual basis and proposed changes 26 shall be reviewed by the dental board to establish a consensus. The dental board shall submit any recommended changes to the 28 infection control guidelines for review to establish a consensus. 29 As necessary, the committee shall consult with the Medical Board 30 of California, the California Board of Podiatric Medicine, the Board of Registered Nursing, and the Board of Vocational Nursing 32 and Psychiatric Technicians, to encourage appropriate consistency 33 in the implementation of this subdivision.

SEC. 7. Section 1958.1 is added to the Business and Professions Code, to read:

1958.1. (a) Notwithstanding any other law, with regard to an individual who is required to register as a sex offender pursuant to Section 290 of the Penal Code, or the equivalent in another state or territory, under military law, or under federal law, all of the following shall apply:

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(1) The committee shall deny an application by the individual for licensure pursuant to this article.

- (2) If the individual is licensed under this article, the committee shall promptly revoke the license of the individual. The committee shall not stay the revocation nor place the license on probation.
- (3) The committee shall not reinstate or reissue the individual's licensure under this article. The committee shall not issue a stay of license denial and place the license on probation.
 - (b) This section shall not apply to any of the following:
- (1) An individual who has been relieved under Section 290.5 of the Penal Code of his or her duty to register as a sex offender, or whose duty to register has otherwise been formally terminated under California law or the law of the jurisdiction that requires his or her registration as a sex offender.
- (2) An individual who is required to register as a sex offender pursuant to Section 290 of the Penal Code solely because of a misdemeanor conviction under Section 314 of the Penal Code. However, nothing in this paragraph shall prohibit the committee from exercising its discretion to discipline a licensee under other provisions of state law based upon the licensee's conviction under Section 314 of the Penal Code.
- (3) Any administrative adjudication proceeding under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that is fully adjudicated prior to January 1, 2013. A petition for reinstatement of a revoked or surrendered license shall be considered a new proceeding for purposes of this paragraph, and the prohibition against reinstating a license to an individual who is required to register as a sex offender shall be applicable.

SEC. 2.

- SEC. 8. Section 2021 of the Business and Professions Code is amended to read:
- 2021. (a) If the board publishes a directory pursuant to Section 112, it may require persons licensed pursuant to this chapter to furnish any information as it may deem necessary to enable it to compile the directory.
- (b) Each licensee shall report to the board each and every change of address within 30 days after each change, giving both the old and new address. If an address reported to the board at the time of application for licensure or subsequently is a post office box, the

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applicant shall also provide the board with a street address. If another address is the licensee's address of record, he or she may request that the second address not be disclosed to the public.

- (c) Each licensee shall report to the board each and every change of name within 30 days after each change, giving both the old and new names.
- (d) The board shall annually send an electronic notice to each applicant and licensee who has chosen to receive correspondence via electronic mail that requests confirmation from the applicant or licensee that his or her electronic mail address is current. An applicant or licensee that does not confirm his or her electronic mail address shall receive correspondence at a mailing address provided pursuant to subdivision (b).

SEC. 3.

- SEC. 9. Section 2064 of the Business and Professions Code is amended to read:
- 2064. Nothing in this chapter shall be construed to prevent a regularly matriculated student undertaking a course of professional instruction in an approved medical school, or to prevent a foreign medical student who is enrolled in an approved medical school or clinical training program in this state, or to prevent students enrolled in a program of supervised clinical training under the direction of an approved medical school pursuant to Section 2104, from engaging in the practice of medicine whenever and wherever prescribed as a part of his or her course of study.

SEC. 4.

- SEC. 10. Section 2184 of the Business and Professions Code is amended to read:
- 29 2184. (a) Each applicant shall obtain on the written 30 examination a passing score, established by the board pursuant to 31 Section 2177.
 - (b) (1) Passing scores on each step of the United States Medical Licensing Examination shall be valid for a period of 10 years from the month of the examination for purposes of qualification for licensure in California.
 - (2) The period of validity provided for in paragraph (1) may be extended by the board for any of the following:
 - (A) For good cause.
- 39 (B) For time spent in a postgraduate training program, including, 40 but not limited to, residency training, clinical training, fellowship

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training, remedial or refresher training, or other training that is intended to maintain or improve medical skills.

- (C) For an applicant who is a physician and surgeon in another state or a Canadian province who is currently and actively practicing medicine in that state or province.
- (3) Upon expiration of the 10-year period plus any extension granted by the board under paragraph (2), the applicant shall pass the Special Purpose Examination of the Federation of State Medical Boards or a clinical competency written examination determined by the board to be equivalent.

SEC. 5.

- SEC. 11. Section 2220 of the Business and Professions Code is amended to read:
- 2220. Except as otherwise provided by law, the board may take action against all persons guilty of violating this chapter. The board shall enforce and administer this article as to physician and surgeon certificate holders, including those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders, and the board shall have all the powers granted in this chapter for these purposes including, but not limited to:
- (a) Investigating complaints from the public, from other licensees, from health care facilities, or from the board that a physician and surgeon may be guilty of unprofessional conduct. The board shall investigate the circumstances underlying a report received pursuant to Section 805 or 805.01 within 30 days to determine if an interim suspension order or temporary restraining order should be issued. The board shall otherwise provide timely disposition of the reports received pursuant to Section 805 and Section 805.01.
- (b) Investigating the circumstances of practice of any physician and surgeon where there have been any judgments, settlements, or arbitration awards requiring the physician and surgeon or his or her professional liability insurer to pay an amount in damages in excess of a cumulative total of thirty thousand dollars (\$30,000) with respect to any claim that injury or damage was proximately caused by the physician's and surgeon's error, negligence, or omission.

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(c) Investigating the nature and causes of injuries from cases which shall be reported of a high number of judgments, settlements, or arbitration awards against a physician and surgeon.

SEC. 6.

- SEC. 12. Section 2424 of the Business and Professions Code is amended to read:
- 2424. (a) The board or the California Board of Podiatric Medicine, as the case may be, shall notify in writing either by certified mail, return receipt requested, or by electronic mail if requested by the licensee, any physician and surgeon or any podiatrist who does not renew his or her license within 60 days from its date of expiration.
- (b) Notwithstanding Section 163.5, any such licensee who does not renew his or her expired license within 90 days of its date of expiration shall pay all the following fees:
 - (1) The renewal fee in effect at the time of renewal.
 - (2) A penalty fee equal to 50 percent of the renewal fee.
- (3) The delinquency fee required by Section 2435 or 2499.5, as the case may be.
- (c) Notwithstanding any other provision of law, the renewal of any expired physician's and surgeon's or podiatrist's license within six months from its date of expiration shall be retroactive to the date of expiration of that license. The division or board, for good cause, may waive the 50 percent penalty fee and may extend retroactivity up to two years from the expiration date of any such license.

SEC. 7.

- *SEC. 13.* Section 2516 of the Business and Professions Code is amended to read:
- 2516. (a) Each licensed midwife who assists, or supervises a student midwife in assisting, in childbirth that occurs in an out-of-hospital setting shall annually report to the Office of Statewide Health Planning and Development. The report shall be submitted no later than March 30, with the first report due in March 2008, for the prior calendar year, in a form specified by the board and shall contain all of the following:
 - (1) The midwife's name and license number.
 - (2) The calendar year being reported.
- 39 (3) The following information with regard to cases in California 40 in which the midwife, or the student midwife supervised by the

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midwife, assisted during the previous year when the intended place of birth at the onset of care was an out-of-hospital setting:

- (A) The total number of clients served as primary caregiver at the onset of care.
- (B) The total number of clients served with collaborative care available through, or given by, a licensed physician and surgeon.
- (C) The total number of clients served under the supervision of a licensed physician and surgeon.
- (D) The number by county of live births attended as primary caregiver.
- (E) The number, by county, of cases of fetal demise, infant deaths, and maternal deaths attended as primary caregiver at the discovery of the demise or death.
- (F) The number of women whose primary care was transferred to another health care practitioner during the antepartum period, and the reason for each transfer.
- (G) The number, reason, and outcome for each elective hospital transfer during the intrapartum or postpartum period.
- (H) The number, reason, and outcome for each urgent or emergency transport of an expectant mother in the antepartum period.
- (I) The number, reason, and outcome for each urgent or emergency transport of an infant or mother during the intrapartum or immediate postpartum period.
- (J) The number of planned out-of-hospital births at the onset of labor and the number of births completed in an out-of-hospital setting.
- (K) The number of planned out-of-hospital births completed in an out-of-hospital setting that were any of the following:
 - (i) Twin births.

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- (ii) Multiple births other than twin births.
- (iii) Breech births.
- (iv) Vaginal births after the performance of a cesarean section.
 - (L) A brief description of any complications resulting in the morbidity or mortality of a mother or a neonate.
- (M) Any other information prescribed by the board in regulations.
- (b) The Office of Statewide Health Planning and Development shall maintain the confidentiality of the information submitted pursuant to this section, and shall not permit any law enforcement

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or regulatory agency to inspect or have copies made of the contents of any reports submitted pursuant to subdivision (a) for any purpose, including, but not limited to, investigations for licensing, certification, or regulatory purposes.

- (c) The office shall report to the board, by April 30, those licensees who have met the requirements of subdivision (a) for that year.
- (d) The board shall send a written notice of noncompliance to each licensee who fails to meet the reporting requirement of subdivision (a). Failure to comply with subdivision (a) will result in the midwife being unable to renew his or her license without first submitting the requisite data to the Office of Statewide Health Planning and Development for the year for which that data was missing or incomplete. The board shall not take any other action against the licensee for failure to comply with subdivision (a).
- (e) The board, in consultation with the office and the Midwifery Advisory Council, shall devise a coding system related to data elements that require coding in order to assist in both effective reporting and the aggregation of data pursuant to subdivision (f). The office shall utilize this coding system in its processing of information collected for purposes of subdivision (f).
- (f) The office shall report the aggregate information collected pursuant to this section to the board by July 30 of each year. The board shall include this information in its annual report to the Legislature.
- (g) Notwithstanding any other provision of law, a violation of this section shall not be a crime.

SEC. 8.

- SEC. 14. Section 2518 of the Business and Professions Code is amended to read:
- 2518. (a) Licenses issued pursuant to this article shall be renewable every two years upon payment of the fee prescribed by Section 2520 and submission of documentation that the licenseholder has completed 36 hours of continuing education in areas that fall within the scope of the practice of midwifery, as specified by the board.
- (b) Each license not renewed shall expire, but may be reinstated within five years from the expiration upon payment of the prescribed fee and upon submission of proof of the applicant's qualifications as the board may require.

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(c) A licensee is exempt from the payment of the renewal fee required by Section 2520 and the requirement for continuing education if the licensee has applied to the board for, and been issued, a retired status license. The holder of a retired status license may not engage in the practice of midwifery.

SEC. 9.

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- SEC. 15. Section 2904.5 of the Business and Professions Code is amended to read:
- 9 2904.5. A psychologist licensed under this chapter is a licentiate 10 for purposes of paragraph (2) of subdivision (a) of Section 805, 11 and thus is a health care provider subject to the provisions of 12 Section 2290.5.

SEC. 10.

- *SEC. 16.* Section 3057.5 of the Business and Professions Code is amended to read:
- 3057.5. Notwithstanding any other provision of this chapter, the board shall permit a graduate of a foreign university who meets all of the following requirements to take the examinations for a certificate of registration as an optometrist:
 - (a) Is over the age of 18 years.
 - (b) Is not subject to denial of a certificate under Section 480.
- (c) Has a degree as a doctor of optometry issued by a university located outside of the United States.

SEC. 11.

- *SEC. 17.* Section 3742 of the Business and Professions Code is amended to read:
- 3742. During the period of any clinical training, a student respiratory care practitioner shall be under the direct supervision of a person holding a valid, current, and unrestricted license issued under this chapter. "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area.

SEC. 12.

- 34 SEC. 18. Section 3750 of the Business and Professions Code is amended to read:
 - 3750. The board may order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license issued under this chapter, for any of the following causes:
 - (a) Advertising in violation of Section 651 or Section 17500.
- 40 (b) Fraud in the procurement of any license under this chapter.

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(c) Knowingly employing unlicensed persons who present themselves as licensed respiratory care practitioners.

- (d) Conviction of a crime that substantially relates to the qualifications, functions, or duties of a respiratory care practitioner. The record of conviction or a certified copy thereof shall be conclusive evidence of the conviction.
- (e) Impersonating or acting as a proxy for an applicant in any examination given under this chapter.
- (f) Negligence in his or her practice as a respiratory care practitioner.
- (g) Conviction of a violation of any of the provisions of this chapter or of any provision of Division 2 (commencing with Section 500), or violating, or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any provision or term of this chapter or of any provision of Division 2 (commencing with Section 500).
- (h) The aiding or abetting of any person to violate this chapter or any regulations duly adopted under this chapter.
- (i) The aiding or abetting of any person to engage in the unlawful practice of respiratory care.
- (j) The commission of any fraudulent, dishonest, or corrupt act which is substantially related to the qualifications, functions, or duties of a respiratory care practitioner.
- (k) Falsifying, or making grossly incorrect, grossly inconsistent, or unintelligible entries in any patient, hospital, or other record.
- (*l*) Changing the prescription of a physician and surgeon, or falsifying verbal or written orders for treatment or a diagnostic regime received, whether or not that action resulted in actual patient harm.
- (m) Denial, suspension, or revocation of any license to practice by another agency, state, or territory of the United States for any act or omission that would constitute grounds for the denial, suspension, or revocation of a license in this state.
- (n) Except for good cause, the knowing failure to protect patients by failing to follow infection control guidelines of the board, thereby risking transmission of blood-borne infectious diseases from licensee to patient, from patient to patient, and from patient to licensee. In administering this subdivision, the board shall consider referencing the standards, regulations, and guidelines of the State Department of Health Services developed pursuant to

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- 1 Section 1250.11 of the Health and Safety Code and the standards,
- 2 regulations, and guidelines pursuant to the California Occupational
- 3 Safety and Health Act of 1973 (Part 1 (commencing with Section
- 4 6300) of Division 5 of the Labor Code) for preventing the
- 5 transmission of HIV, hepatitis B, and other blood-borne pathogens
- 6 in health care settings. As necessary, the board shall consult with
- 7 the California Medical Board, the Board of Podiatric Medicine,
- 8 the Board of Dental Examiners, the Board of Registered Nursing,
- 9 and the Board of Vocational Nursing and Psychiatric Technicians,
- to encourage appropriate consistency in the implementation of thissubdivision.

The board shall seek to ensure that licensees are informed of the responsibility of licensees and others to follow infection control guidelines, and of the most recent scientifically recognized safeguards for minimizing the risk of transmission of blood-borne infectious diseases.

- (o) Incompetence in his or her practice as a respiratory care practitioner.
- (p) A pattern of substandard care or negligence in his or her practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

SEC. 13.

- SEC. 19. Section 3750.5 of the Business and Professions Code is amended to read:
- 3750.5. In addition to any other grounds specified in this chapter, the board may deny, suspend, place on probation, or revoke the license of any applicant or licenseholder who has done any of the following:
- (a) Obtained, possessed, used, or administered to himself or herself in violation of law, or furnished or administered to another, any controlled substances as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 2 (commencing with Section 4015) of Chapter 9, except as directed by a licensed physician and surgeon, dentist, podiatrist, or other authorized health care provider, or illegally possessed any associated paraphernalia.
- (b) Used any controlled substance as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 2 (commencing with

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1 Section 4015) of Chapter 9 of this code, or alcoholic beverages, 2 to an extent or in a manner dangerous or injurious to himself or 3 herself, or to others, or that impaired his or her ability to conduct 4 with safety the practice authorized by his or her license.

- (c) Applied for employment or worked in any health care profession or environment while under the influence of alcohol.
- (d) Been convicted of a criminal offense involving the consumption or self-administration of any of the substances described in subdivisions (a) and (b), or the possession of, or falsification of a record pertaining to, the substances described in subdivision (a), in which event the record of the conviction is conclusive evidence thereof.
- (e) Been committed or confined by a court of competent jurisdiction for intemperate use of or addiction to the use of any of the substances described in subdivisions (a), (b), and (c), in which event the court order of commitment or confinement is prima facie evidence of that commitment or confinement.
- (f) Falsified, or made grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a).
- SEC. 20. Section 4209 of the Business and Professions Code is amended to read:
- 4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
- (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
- (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. *Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.*
- (c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, *provided that*

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the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

- SEC. 21. Section 4300.1 is added to the Business and Professions Code, to read:
- 4300.1. The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.
- SEC. 22. Section 4600 of the Business and Professions Code is amended to read:
- 4600. As used in this chapter, the following terms shall have the following meanings:
- (a) "Approved school" or "approved massage school" means a school approved by the council that meets minimum standards for training and curriculum in massage and related subjects and that meets any of the following requirements:
- (1) Is approved by the Bureau for Private Postsecondary Education.
 - (2) Is approved by the Department of Consumer Affairs.
- (3) Is an institution accredited by the Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges of the Western Association of Schools and Colleges and that is one of the following:
- (A) A public institution.

- (B) An institution incorporated and lawfully operating as a nonprofit public benefit corporation pursuant to Part 2 (commencing with Section 5110) of Division 2 of Title 1 of the Corporations Code, and that is not managed by any entity for profit.
- (C) A for-profit institution.
- 38 (D) An institution that does not meet all of the criteria in 39 subparagraph (B) that is incorporated and lawfully operating as a 40 nonprofit public benefit corporation pursuant to Part 2

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(commencing with Section 5110) of Division 2 of Title 1 of the Corporations Code, that has been in continuous operation since April 15, 1997, and that is not managed by any entity for profit.

- (4) Is a college or university of the state higher education system, as defined in Section 100850 of the Education Code.
- (5) Is a school of equal or greater training that is recognized by the corresponding agency in another state or accredited by an agency recognized by the United States Department of Education.
- (b) "Compensation" means the payment, loan, advance, donation, contribution, deposit, or gift of money or anything of value.
- (c) "Massage therapist," "bodyworker," "bodywork therapist," or "massage and bodywork therapist" means a person who is certified by the California Massage Therapy Council under subdivision (c) of Section 4601 and who administers massage for compensation.
- (d) "Massage practitioner," "bodywork practitioner," or "massage and bodywork practitioner" means a person who is certified by the California Massage Therapy Council under subdivision (b) of Section 4601 and who administers massage for compensation.
- (e) "Council" means the California Massage Therapy Council created pursuant to this chapter, which shall be a nonprofit organization exempt from taxation under Section 501(c)(3) of Title 26 of the United States Code. The council may commence activities as authorized by this section once it has submitted a request to the Internal Revenue Service seeking this exemption. Whenever the term "organization" is used in this chapter, it shall mean the council, except where the context indicates otherwise.
- (f) "Registered school" means a school approved by the council that meets minimum standards for training and curriculum in massage and related subjects and that either is approved by the Bureau for Private Postsecondary Education or the Department of Consumer Affairs, or is an institution accredited by the senior commission or the junior commission of the Western Association of Schools and Colleges as defined in paragraph (3) of subdivision (a), is a college or university of the state higher education system as defined in Section 100850 of the Education Code, or is a school of equal or greater training that is approved by the corresponding agency in another state.

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(g) For purposes of this chapter, the terms "massage" and "bodywork" shall have the same meaning.

- (h) "Operator of a massage business" means a person, whether owner or nonowner, who manages or operates a massage business.
- SEC. 23. Section 4601 of the Business and Professions Code is amended to read:
- 4601. (a) The council shall issue a certificate under this chapter to an applicant who satisfies the requirements of this chapter.
- (b) (1) In order to obtain certification as a massage practitioner, an applicant shall submit a written application and provide the council with satisfactory evidence that he or she meets all of the following requirements:
 - (A) The applicant is 18 years of age or older.

- (B) The applicant has successfully completed, at a single approved school, curricula in massage and related subjects totaling a minimum of 250 hours, or the credit unit equivalent, that incorporates appropriate school assessment of student knowledge and skills. Included in the hours shall be instruction addressing anatomy and physiology, contraindications, health and hygiene, and business and ethics, with at least 100 hours of the required minimum 250 hours devoted to these curriculum areas.
 - (C) All fees required by the council have been paid.
- (2) New certificates shall not be issued pursuant to this subdivision after December 31, 2015. Certificates issued pursuant to this section or subdivision (a) or (c) of Section 4604 on or before December 31, 2015, shall, after December 31, 2015, be renewed without any additional educational requirements, provided that the certificate holder continues to be qualified pursuant to this chapter.
- (c) In order to obtain certification as a massage therapist, an applicant shall submit a written application and provide the council with satisfactory evidence that he or she meets all of the following requirements:
 - (1) The applicant is 18 years of age or older.
- (2) The applicant satisfies at least one of the following requirements:
- (A) He or she has successfully completed the curricula in massage and related subjects totaling a minimum of 500 hours, *or the credit unit equivalent*. Of this 500 hours, a minimum of 250 hours shall be from approved schools. The remaining 250 hours required may be secured either from approved or registered schools,

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or from continuing education providers approved by, or registered with, the council or the Department of Consumer Affairs. After December 31, 2015, applicants may only satisfy the curricula in massage and related subjects from approved schools.

- (B) The applicant has successfully completed, at a single approved school, a curricula in massage and related subjects totaling a minimum of 250 hours that incorporates appropriate school assessment of student knowledge and skills. Included in the hours shall be instruction addressing anatomy and physiology, contraindications, health and hygiene, and business and ethics, with at least 100 hours of the required minimum 250 hours devoted to these curriculum areas. The applicant has also passed a massage and bodywork competency assessment examination that meets generally recognized psychometric principles and standards, and that is approved by the board. The successful completion of this examination may have been accomplished before the date the council is authorized by this chapter to begin issuing certificates.
 - (3) All fees required by the council have been paid.
- (d) The council shall issue a certificate to an applicant who meets the other qualifications of this chapter and holds a current and valid registration, certification, or license from any other state whose licensure requirements meet or exceed those defined within this chapter. The council shall have discretion to give credit for comparable academic work completed by an applicant in a program outside of California.
- (e) An applicant applying for a massage therapist certificate shall file with the council a written application provided by the council, showing to the satisfaction of the council that he or she meets all of the requirements of this chapter.
- (f) Any certification issued under this chapter shall be subject to renewal every two years in a manner prescribed by the council, and shall expire unless renewed in that manner. The council may provide for the late renewal of a license.
- (g) (1) The council shall have the responsibility to determine that the school or schools from which an applicant has obtained the education required by this chapter meet the requirements of this chapter. If the council has any reason to question whether or not the applicant received the education that is required by this chapter from the school or schools that the applicant is claiming,

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the council shall investigate the facts to determine that the applicant received the required education prior to issuing a certificate.

- (2) For purposes of paragraph (1) and any other provision of this chapter for which the council is authorized to receive factual information as a condition of taking any action, the council shall have the authority to conduct oral interviews of the applicant and others or to make any investigation deemed necessary to establish that the information received is accurate and satisfies any criteria established by this chapter.
- (h) The certificate issued pursuant to this chapter, as well as any identification card issued by the council, are the exclusive property of the council and shall be surrendered to the council by any certificate holder who is suspended or revoked.
- SEC. 24. Section 4603.7 of the Business and Professions Code is amended to read:
- 4603.7. A certificate holder shall include the name under which he or she is certified and his or her certificate number in any and all advertising and shall display his or her *original* certificate at his or her place of business. A certificate holder shall have his or her identification card in his or her possession while providing massage services.
- SEC. 25. Section 4612 of the Business and Professions Code is amended to read:
- 4612. (a) (1) The holder of a certificate issued pursuant to this chapter shall have the right to practice massage, consistent with this chapter and the qualifications established by his or her certification, in any city, county, or city and county in this state and shall not be required to obtain any other license, permit, or other authorization, except as provided in this section, to engage in that practice.
- (2) Notwithstanding any other provision of law, a city, county, or city and county shall not enact an ordinance that requires a license, permit, or other authorization to provide massage for compensation by an individual who is certified pursuant to this chapter and who is practicing consistent with the qualifications established by his or her certification, or by a massage business or massage establishment that employs or uses only persons who are certified pursuant to this chapter to provide massage for compensation. No provision of any ordinance enacted by a city, county, or city and county that is in effect before the effective date

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of this chapter, and that requires a license, permit, or other authorization to provide massage for compensation, may be enforced against an individual who is certified pursuant to this chapter or against a massage business or massage establishment that employs or uses only persons who are certified pursuant to this chapter to provide massage for compensation.

- (3) Except as provided in subdivision (b), nothing in this section shall be interpreted to prevent a city, county, or city and county from adopting or enforcing any local ordinance that provides for reasonable health and safety requirements for massage establishments or businesses. Subdivision (b) shall not apply to any massage establishment or business that employs or uses persons to provide massage services who are not certified pursuant to this chapter.
- (b) (1) This subdivision shall apply only to massage establishments or businesses that are sole proprietorships, where the sole proprietor is certified pursuant to this chapter, and to massage establishments or businesses that employ or use only persons certified pursuant to this chapter to provide massage services. For purposes of this subdivision, a sole proprietorship is a business where the owner is the only person employed by that business to provide massage services.
- (2) (A) Any massage establishment or business described in paragraph (1) shall maintain on its premises evidence for review by local authorities that demonstrates that all persons providing massage services are certified.
- (B) Nothing in this section shall preclude a city, county, or city and county from including in a local ordinance a provision that requires a business described in paragraph (1) to file copies or provide other evidence of the certificates held by the persons who are providing massage services at the business.
- (3) A city, county, or city and county may charge a massage business or establishment a business licensing fee, provided that the fee shall be no-different higher than the fee that is uniformly applied to all other individuals and businesses providing professional services, as defined in subdivision (a) of Section 13401 of the Corporations Code.
- (4) Nothing in this section shall prohibit a city, county, or city and county from enacting ordinances, regulations, rules, requirements, restrictions, land use regulations, moratoria,

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conditional use permits, or zoning requirements applicable to an individual certified pursuant to this chapter or to a massage establishment or business that uses only individuals who are certified pursuant to this chapter to provide massage for compensation, provided that, unless otherwise exempted by this chapter, these ordinances, regulations, rules, requirements, restrictions, land use regulations, moratoria, conditional use permits, and zoning requirements shall be no different than the requirements that are uniformly applied to all other individuals and businesses providing professional services, as defined in subdivision (a) of Section 13401 of the Corporations Code. No provision of any ordinance, regulation, rule, requirement, restriction, land use regulation, moratoria, conditional use permit, or zoning requirement enacted by a city, county, or city and county that is in effect before the effective date of this chapter, and that is inconsistent with this paragraph, may be enforced against an individual who is certified pursuant to this chapter or against a massage business or massage establishment that uses only individuals who are certified pursuant to this chapter to provide massage for compensation.

(5) Local building code or physical facility requirements applicable to massage establishments or businesses shall not require additional restroom, shower, or other facilities that are not uniformly applicable to other professional or personal service businesses, nor shall building or facility requirements be adopted that (A) require unlocked doors when there is no staff available to ensure security for clients and massage staff who are behind closed doors, or (B) require windows that provide a view into massage rooms that interfere with the privacy of clients of the massage business.

(6) A city, county, or city and county may adopt reasonable health and safety requirements with respect to massage establishments or businesses, including, but not limited to, requirements for cleanliness of massage rooms, towels and linens, and reasonable attire and personal hygiene requirements for persons providing massage services, provided that nothing in this paragraph shall be interpreted to authorize adoption of local ordinances that impose additional qualifications, such as medical examinations, background checks, or other criteria, upon any person certified pursuant to this chapter.

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(7) Nothing in this section shall preclude a city, county, or city and county from doing any of the following:

- (A) Requiring an applicant for a business license to operate a massage business or establishment to fill out an application that requests the applicant to provide relevant information, as long as the information requested is the same as that required of other individuals and professionals providing professional services as defined in subdivision (a) of Section 13401 of the Corporations Code.
- (B) Making reasonable investigations into the information so provided.
- (C) Denying or restricting a business license if the applicant has provided materially false information.
- (c) An owner or operator of a massage business or establishment subject to subdivision (b) who is certified pursuant to this chapter shall be responsible for the conduct of all employees or independent contractors working on the premises of the business. Failure to comply with this chapter may result in revocation of the owner's or operator's certificate in accordance with Section 4603. Nothing in this section shall preclude a local ordinance from authorizing suspension, revocation, or other restriction of a license or permit issued to a massage establishment or business if violations of this chapter, or of the local ordinance, occur on the business premises.
- (d) Nothing in this section shall preclude a city, county, or city and county from adopting a local ordinance that is applicable to massage businesses or establishments described in paragraph (1) of subdivision (b) and that does either of the following:
- (1) Provides that duly authorized officials of the city, county, or city and county have the right to conduct reasonable inspections, during regular business hours, to ensure compliance with this chapter, the local ordinance, or other applicable fire and health and safety requirements.
- (2) Requires an owner or operator to notify the city, county, or city and county of any intention to rename, change management, or convey the business to another person.
- (e) Nothing in this chapter shall be construed to preclude a city, county, or city and county from requiring a background check of an owner or operator of a massage establishment who owns 5 percent or more of a massage business or massage establishment and who is not certified pursuant to this chapter. The background

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- check may consist of an application that requires the include, but 2 is not limited to, a criminal background check, including requiring 3 submission of fingerprints for a state and federal criminal 4 background check, submission of an application that requires the 5 applicant to state information, including, but not limited to, the applicant's business, occupation, and employment history for the 6 7 five 10 years preceding the date of application, the inclusive dates 8 of same, and the name and address of any massage business or other like establishment owned or operated by any person who is subject to the background check requirement of this subdivision. 10 If a noncertified owner's or operator's background check results 11 12 in a finding that the city, county, or city and county determines is 13 relevant to owning or operating a massage establishment, the 14 provisions of subdivisions (a) and (b) shall not apply to that 15 establishment and the city, county, or city and county may regulate that establishment in any manner it deems proper that is in 16 17 accordance with the law.
 - SEC. 14.

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- *SEC. 26.* Section 4980.04 of the Business and Professions Code is amended to read:
- 4980.04. This chapter shall be known and may be cited as the Licensed Marriage and Family Therapist Act.
 - SEC. 15.
- SEC. 27. Section 4980.34 of the Business and Professions Code is amended to read:
- 4980.34. It is the intent of the Legislature that the board employ its resources for each and all of the following functions:
- (a) The licensing of marriage and family therapists, clinical social workers, professional clinical counselors, and educational psychologists.
- (b) The development and administration of licensing examinations and examination procedures, as specified, consistent with prevailing standards for the validation and use of licensing and certification tests. Examinations shall measure knowledge and abilities demonstrably important to the safe, effective practice of the profession.
- 37 (c) Enforcement of laws designed to protect the public from 38 incompetent, unethical, or unprofessional practitioners.
 - (d) Consumer education.

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SEC. 16.

2 SEC. 28. Section 4980.398 of the Business and Professions 3 Code is amended to read:

4980.398. (a) Each applicant who had previously taken and passed the standard written examination but had not passed the clinical vignette examination shall also obtain a passing score on the clinical examination in order to be eligible for licensure.

- (b) An applicant who had previously failed to obtain a passing score on the standard written examination shall obtain a passing score on the California law and ethics examination and the clinical examination.
- (c) An applicant who had obtained eligibility for the standard written examination shall take the California law and ethics examination and the clinical examination.
 - (d) This section shall become operative on January 1, 2013. SEC. 17.
- SEC. 29. Section 4980.399 of the Business and Professions Code is amended to read:
- 4980.399. (a) Except as provided in *subdivision* (a) of Section 4980.398, each applicant and registrant shall obtain a passing score on a board-administered California law and ethics examination in order to qualify for licensure.
- (b) A registrant shall participate in a board-administered California law and ethics examination prior to his or her registration renewal.
- (c) If an applicant fails the California law and ethics examination, he or she may retake the examination, upon payment of the required fees, without further application except as provided in subdivision (d).
- (d) If a registrant fails to obtain a passing score on the California law and ethics examination described in subdivision (a) within his or her first renewal period on or after the operative date of this section, he or she shall complete, at a minimum, a 12-hour course in California law and ethics in order to be eligible to participate in the California law and ethics examination. Registrants shall only take the 12-hour California law and ethics course once during a renewal period. The 12-hour law and ethics course required by the section shall be taken through a board-approved continuing education provider, a county, state or governmental entity, or a college or university.

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(e) The board shall not issue a subsequent registration number unless the registrant has passed the California law and ethics examination.

- (f) This section shall become operative on January 1, 2013.
- SEC. 30. Section 4980.43 of the Business and Professions Code is amended to read:
- 4980.43. (a) Prior to applying for licensure examinations, each applicant shall complete experience that shall comply with the following:
- (1) A minimum of 3,000 hours completed during a period of at least 104 weeks.
 - (2) Not more than 40 hours in any seven consecutive days.
- (3) Not less than 1,700 hours of supervised experience completed subsequent to the granting of the qualifying master's or doctoral degree.
- (4) Not more than 1,300 hours of supervised experience obtained prior to completing a master's or doctoral degree.

The applicant shall not be credited with more than 750 hours of counseling and direct supervisor contact prior to completing the master's or doctoral degree.

- (5) No hours of experience may be gained prior to completing either 12 semester units or 18 quarter units of graduate instruction and becoming a trainee except for personal psychotherapy.
- (6) No hours of experience may be gained more than six years prior to the date the application for examination eligibility was filed, except that up to 500 hours of clinical experience gained in the supervised practicum required by subdivision (c) of Section 4980.37 and subparagraph (B) of paragraph (1) of subdivision (d) of Section 4980.36 shall be exempt from this six-year requirement.
- (7) Not more than a combined total of 1,000 hours of experience in the following:
 - (A) Direct supervisor contact.
- (B) Professional enrichment activities. For purposes of this chapter, "professional enrichment activities" include the following:
- (i) Workshops, seminars, training sessions, or conferences directly related to marriage and family therapy attended by the applicant that are approved by the applicant's supervisor. An applicant shall have no more than 250 hours of verified attendance at these workshops, seminars, training sessions, or conferences.

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(ii) Participation by the applicant in personal psychotherapy, which includes group, marital or conjoint, family, or individual psychotherapy by an appropriately licensed professional. An applicant shall have no more than 100 hours of participation in personal psychotherapy. The applicant shall be credited with three hours of experience for each hour of personal psychotherapy.

- (8) Not more than 500 hours of experience providing group therapy or group counseling.
- (9) For all hours gained on or after January 1, 2012, not more than 500 hours of experience in the following:
- (A) Experience administering and evaluating psychological tests, writing clinical reports, writing progress notes, or writing process notes.
 - (B) Client centered advocacy.
- (10) Not less than 500 total hours of experience in diagnosing and treating couples, families, and children. For up to 150 hours of treating couples and families in conjoint therapy, the applicant shall be credited with two hours of experience for each hour of therapy provided.
- (11) Not more than 375 hours of experience providing personal psychotherapy, crisis counseling, or other counseling services via telehealth in accordance with Section 2290.5.
- (12) It is anticipated and encouraged that hours of experience will include working with elders and dependent adults who have physical or mental limitations that restrict their ability to carry out normal activities or protect their rights.

This subdivision shall only apply to hours gained on and after January 1, 2010.

(b) All applicants, trainees, and registrants shall be at all times under the supervision of a supervisor who shall be responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who shall be responsible to the board for compliance with all laws, rules, and regulations governing the practice of marriage and family therapy. Supervised experience shall be gained by interns and trainees either as an employee or as a volunteer. The requirements of this chapter regarding gaining hours of experience and supervision are applicable equally to employees and volunteers. Experience shall not be gained by interns or trainees as an independent contractor.

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(1) If employed, an intern shall provide the board with copies of the corresponding W-2 tax forms for each year of experience claimed upon application for licensure.

- (2) If volunteering, an intern shall provide the board with a letter from his or her employer verifying the intern's employment as a volunteer upon application for licensure.
- (c) Supervision—Except for experience gained pursuant to subparagraph (B) of paragraph (7) of subdivision (a), supervision shall include at least one hour of direct supervisor contact in each week for which experience is credited in each work setting, as specified:
- (1) A trainee shall receive an average of at least one hour of direct supervisor contact for every five hours of client contact in each setting.
- (2) An individual supervised after being granted a qualifying degree shall receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of client contact is gained in each setting. No more than five hours of supervision, whether individual or group, shall be credited during any single week.
- (3) For purposes of this section, "one hour of direct supervisor contact" means one hour per week of face-to-face contact on an individual basis or two hours per week of face-to-face contact in a group.
- (4) Direct supervisor contact shall occur within the same week as the hours claimed.
- (5) Direct supervisor contact provided in a group shall be provided in a group of not more than eight supervisees and in segments lasting no less than one continuous hour.
- (6) Notwithstanding paragraph (3), an intern working in a governmental entity, a school, a college, or a university, or an institution that is both nonprofit and charitable may obtain the required weekly direct supervisor contact via two-way, real-time videoconferencing. The supervisor shall be responsible for ensuring that client confidentiality is upheld.
- (7) All experience gained by a trainee shall be monitored by the supervisor as specified by regulation.
- (d) (1) A trainee may be credited with supervised experience completed in any setting that meets all of the following:

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(A) Lawfully and regularly provides mental health counseling or psychotherapy.

- (B) Provides oversight to ensure that the trainee's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.
- (C) Is not a private practice owned by a licensed marriage and family therapist, a licensed psychologist, a licensed clinical social worker, a licensed physician and surgeon, or a professional corporation of any of those licensed professions.
- (2) Experience may be gained by the trainee solely as part of the position for which the trainee volunteers or is employed.
- (e) (1) An intern may be credited with supervised experience completed in any setting that meets both of the following:
- (A) Lawfully and regularly provides mental health counseling or psychotherapy.
- (B) Provides oversight to ensure that the intern's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.
- (2) An applicant shall not be employed or volunteer in a private practice, as defined in subparagraph (C) of paragraph (1) of subdivision (d), until registered as an intern.
- (3) While an intern may be either a paid employee or a volunteer, employers are encouraged to provide fair remuneration to interns.
- (4) Except for periods of time during a supervisor's vacation or sick leave, an intern who is employed or volunteering in private practice shall be under the direct supervision of a licensee that has satisfied the requirements of subdivision (g) of Section 4980.03. The supervising licensee shall either be employed by and practice at the same site as the intern's employer, or shall be an owner or shareholder of the private practice. Alternative supervision may be arranged during a supervisor's vacation or sick leave if the supervision meets the requirements of this section.
- (5) Experience may be gained by the intern solely as part of the position for which the intern volunteers or is employed.
- (f) Except as provided in subdivision (g), all persons shall register with the board as an intern in order to be credited for postdegree hours of supervised experience gained toward licensure.

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(g) Except when employed in a private practice setting, all postdegree hours of experience shall be credited toward licensure so long as the applicant applies for the intern registration within 90 days of the granting of the qualifying master's or doctoral degree and is thereafter granted the intern registration by the board.

- (h) Trainees, interns, and applicants shall not receive any remuneration from patients or clients, and shall only be paid by their employers.
- (i) Trainees, interns, and applicants shall only perform services at the place where their employers regularly conduct business, which may include performing services at other locations, so long as the services are performed under the direction and control of their employer and supervisor, and in compliance with the laws and regulations pertaining to supervision. Trainees and interns shall have no proprietary interest in their employers' businesses and shall not lease or rent space, pay for furnishings, equipment or supplies, or in any other way pay for the obligations of their employers.
- (j) Trainees, interns, or applicants who provide volunteered services or other services, and who receive no more than a total, from all work settings, of five hundred dollars (\$500) per month as reimbursement for expenses actually incurred by those trainees, interns, or applicants for services rendered in any lawful work setting other than a private practice shall be considered an employee and not an independent contractor. The board may audit applicants who receive reimbursement for expenses, and the applicants shall have the burden of demonstrating that the payments received were for reimbursement of expenses actually incurred.
- (k) Each educational institution preparing applicants for licensure pursuant to this chapter shall consider requiring, and shall encourage, its students to undergo individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Each supervisor shall consider, advise, and encourage his or her interns and trainees regarding the advisability of undertaking individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Insofar as it is deemed appropriate and is desired by the applicant, the educational institution and supervisors are encouraged to assist the applicant in locating that counseling or psychotherapy at a reasonable cost.

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1 SEC. 31. Section 4980.44 of the Business and Professions Code 2 is amended to read:

- 4980.44. An unlicensed marriage and family therapist intern employed under this chapter shall comply with the following requirements:
- (a) Possess, at a minimum, a master's degree as specified in Section 4980.36 or 4980.37, as applicable.
- (b) Register with the board prior to performing any duties, except as otherwise provided in subdivision (g) of Section 4980.43.
- (c) Prior to performing any professional services, inform each client or patient that he or she is an unlicensed marriage and family therapist registered intern, provide his or her registration number and the name of his or her employer, and indicate whether he or she is under the supervision of a licensed marriage and family therapist, licensed clinical social worker, *licensed professional clinical counselor*, licensed psychologist, or a licensed physician and surgeon certified in psychiatry by the American Board of Psychiatry and Neurology.
- (d) (1) Any advertisement by or on behalf of a marriage and family therapist registered intern shall include, at a minimum, all of the following information:
- (A) That he or she is a marriage and family therapist registered intern.
 - (B) The intern's registration number.
 - (C) The name of his or her employer.
 - (D) That he or she is supervised by a licensed person.
- (2) The abbreviation "MFTI" shall not be used in an advertisement unless the title "marriage and family therapist registered intern" appears in the advertisement.
- SEC. 32. Section 4980.48 of the Business and Professions Code is amended to read:
- 4980.48. (a) A trainee shall, prior to performing any professional services, inform each client or patient that he or she is an unlicensed marriage and family therapist trainee, provide the name of his or her employer, and indicate whether he or she is under the supervision of a licensed marriage and family therapist, a licensed clinical social worker, *a licensed professional clinical counselor*, a licensed psychologist, or a licensed physician certified in psychiatry by the American Board of Psychiatry and Neurology.

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(b) Any person that advertises services performed by a trainee shall include the trainee's name, the supervisor's license designation or abbreviation, and the supervisor's license number.

- (c) Any advertisement by or on behalf of a marriage and family therapist trainee shall include, at a minimum, all of the following information:
 - (1) That he or she is a marriage and family therapist trainee.
 - (2) The name of his or her employer.
 - (3) That he or she is supervised by a licensed person.

10 SEC. 18.

- SEC. 33. Section 4980.78 of the Business and Professions Code is amended to read:
- 4980.78. (a) This section applies to persons who apply for licensure or registration on or after January 1, 2014.
- (b) For purposes of Sections 4980.72 and 4980.74, education is substantially equivalent if all of the following requirements are met:
- (1) The degree is obtained from a school, college, or university accredited by an accrediting agency recognized by the United States Department of Education and consists of, at a minimum, 48 semester or 72 quarter units, including, but not limited to, both of the following:
- (A) Six semester or nine quarter units of practicum, including, but not limited to, a minimum of 150 hours of face-to-face counseling.
- (B) Twelve semester or 18 quarter units in the areas of marriage, family, and child counseling and marital and family systems approaches to treatment, as specified in subparagraph (A) of paragraph (1) of subdivision (d) of Section 4980.36.
- (2) The applicant completes any units and course content requirements under subdivision (d) of Section 4980.36 not already completed in his or her education.
- (3) The applicant completes credit level coursework from a degree-granting institution that provides all of the following:
- (A) Instruction regarding the principles of mental health recovery-oriented care and methods of service delivery in recovery model practice environments.
- (B) An understanding of various California cultures and the social and psychological implications of socioeconomic position.

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(C) Structured meeting with various consumers and family members of consumers of mental health services to enhance understanding of their experience of mental illness, treatment, and recovery.

- (D) Instruction in addiction and co-occurring substance abuse and mental health disorders, as specified in subparagraph (I) of paragraph (2) of subdivision (d) of Section 4980.36.
- (4) The applicant completes an 18-hour course in California law and professional ethics. The content of the course shall include, but not be limited to, advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous patients, psychotherapist-patient privilege, recordkeeping, patient access to records, the Health Insurance Portability and Accountability Act state and federal laws relating to confidentiality of patient health information, dual relationships, child abuse, elder dependent adult abuse, online therapy, reimbursement, civil liability, disciplinary actions unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, therapist disclosures to patients, differences in legal and ethical standards in different types of work settings, and licensing law and licensing process.
- (5) The applicant's degree title need not be identical to that required by subdivision (b) of Section 4980.36.

SEC. 19.

- SEC. 34. Section 4980.80 of the Business and Professions Code is amended to read:
- 4980.80. (a) This section applies to persons who apply for licensure between January 1, 2010, and December 31, 2013, inclusive.
- (b) The board may issue a license to a person who, at the time of application, holds a valid license issued by a board of marriage counselor examiners, marriage therapist examiners, or corresponding authority of any state, if all of the following requirements are satisfied:
- 36 (1) The person has held that license for at least two years 37 immediately preceding the date of application.
 - (2) The education and supervised experience requirements are substantially the equivalent of this chapter.
 - (3) The person complies with Section 4980.76, if applicable.

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(4) The person successfully completes the board administered licensing examinations as specified by subdivision (d) of Section 4980.40 and pays the fees specified.

- (5) The person completes all of the following coursework or training:
- (A) (i) An applicant who completed a two semester or three quarter unit course in law and professional ethics for marriage and family therapists that does not meet the requirements of Section 4980.41 as part of his or her qualifying degree shall complete an 18-hour course in California law and professional ethics that includes, but is not limited to, the following subjects: advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous patients, psychotherapist-patient privilege, recordkeeping, patient access to records, requirements of the Health Insurance Portability and Accountability Act of 1996, state and federal laws relating to the confidentiality of patient health information, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to patients.
- (ii) An applicant who has not completed a two semester or three quarter unit course in law and professional ethics for marriage and family therapists that included areas of study as specified in Section 4980.41 as part of his or her qualifying degree, shall complete a two semester or three quarter unit course in California law and professional ethics that includes, at minimum, the areas of study specified in Section 4980.41.
- (B) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28 and any regulations promulgated thereunder.
- (C) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25 and any regulations promulgated thereunder.
- (D) A minimum of 15 contact hours of training or coursework in alcoholism and other chemical substance dependency as specified by regulation.
- (E) (i) Instruction in spousal or partner abuse assessment, detection, and intervention. This instruction may be taken either

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in fulfillment of other requirements for licensure or in a separate course.

- (ii) A minimum of 15 contact hours of coursework or training in spousal or partner abuse assessment, detection, and intervention strategies.
- (F) A minimum of a two semester or three quarter unit survey course in psychological testing. This course may be taken either in fulfillment of other requirements for licensure or in a separate course.
- (G) A minimum of a two semester or three quarter unit survey course in psychopharmacology. This course may be taken either in fulfillment of other requirements for licensure or in a separate course.
- (H) With respect to human sexuality, alcoholism and other chemical substance dependency, spousal or partner abuse assessment, detection, and intervention, psychological testing, and psychopharmacology, the board may accept training or coursework acquired out of state.
- (c) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 20.

- SEC. 35. Section 4984.4 of the Business and Professions Code is amended to read:
- 4984.4. A license that is not renewed within three years after its expiration may not be renewed, restored, reinstated, or reissued; however, the former licensee may apply for and obtain a new license if the following criteria are satisfied:
- (a) No fact, circumstance, or condition exists that, if the license were issued, would constitute grounds for its revocation or suspension.
- (b) He or she submits an application for examination eligibility and the fee for that application.
- (c) He or she takes and passes the current licensing examinations.
 - (d) He or she submits the fee for initial license issuance.
- 37 (e) He or she complies with the fingerprint requirements 38 established by board regulation.

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SEC. 21.

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2 SEC. 36. Section 4989.16 of the Business and Professions Code 3 is amended to read:

- 4989.16. (a) A person appropriately credentialed by the Commission on Teacher Credentialing may perform the functions authorized by that credential in a public school without a license issued under this chapter by the board.
- (b) Nothing in this chapter shall be construed to constrict, limit, or withdraw the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 10 (commencing with Section 2700)), the Psychology Licensing Law 12 (Chapter 6.6 (commencing with Section 2900)), the Licensed 13 Marriage and Family Therapist Practice Act (Chapter 13 14 (commencing with Section 4980)), or the Clinical Social Worker Practice Act (Chapter 14 (commencing with Section 4991)). 16

SEC. 22.

- SEC. 37. Section 4989.42 of the Business and Professions Code is amended to read:
- 4989.42. A license that is not renewed within three years after its expiration may not be renewed, restored, reinstated, or reissued thereafter. A former licensee may apply for a new license if he or she satisfies all of the following requirements:
- (a) No fact, circumstance, or condition exists that, if the license were issued, would constitute grounds for its revocation or suspension.
- (b) Payment of the fees that would be required if he or she were applying for a license for the first time.
 - (c) Passage of the current licensure examination.
- (d) He or she complies with the fingerprint requirements established by board regulation.

SEC. 23.

- SEC. 38. Section 4992.07 of the Business and Professions Code is amended to read:
- 4992.07. (a) An applicant who had previously taken and passed the standard written examination but had not passed the clinical vignette examination shall also obtain a passing score on the clinical examination in order to be eligible for licensure.
- 38 (b) An applicant who had previously failed to obtain a passing 39 score on the standard written examination shall obtain a passing

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score on the California law and ethics examination and the clinicalexamination.

- (c) An applicant who had obtained eligibility for the standard written examination shall take the California law and ethics examination and the clinical examination.
- (d) This section shall become operative on January 1, 2013. SEC. 24.
- SEC. 39. Section 4992.09 of the Business and Professions Code is amended to read:
- 4992.09. (a) Except as provided in *subdivision* (a) of Section 4992.07, an applicant and registrant shall obtain a passing score on a board-administered California law and ethics examination in order to qualify for licensure.
- (b) A registrant shall participate in a board-administered California law and ethics examination prior to his or her registration renewal.
- (c) If an applicant fails the California law and ethics examination, he or she may retake the examination, upon payment of the required fees, without further application except for as provided in subdivision (d).
- (d) If a registrant fails to obtain a passing score on the California law and ethics examination described in subdivision (a) within his or her first renewal period on or after the operative date of this section, he or she shall complete, at a minimum, a 12-hour course in California law and ethics in order to be eligible to participate in the California law and ethics examination. Registrants shall only take the 12-hour California law and ethics course once during a renewal period. The 12-hour law and ethics course required by the section shall be taken through a board-approved continuing education provider, a county, state or governmental entity, or a college or university.
- (e) The board shall not issue a subsequent registration number unless the registrant has passed the California law and ethics examination.
- (f) This section shall become operative on January 1, 2013. SEC. 25.
- 37 SEC. 40. Section 4996.6 of the Business and Professions Code is amended to read:

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4996.6. (a) Licenses issued under this chapter shall expire no more than 24 months after the issue date. The expiration date of the original license shall be set by the board.

- (b) To renew an unexpired license, the licensee shall, on or before the expiration date of the license, complete the following actions:
 - (1) Apply for a renewal on a form prescribed by the board.
 - (2) Pay a two-year renewal fee prescribed by the board.
- (3) Certify compliance with the continuing education requirements set forth in Section 4996.22.
- (4) Notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.
- (c) To renew an expired license within three years of its expiration, the licensee shall, as a condition precedent to renewal, complete all of the actions described in subdivision (b) and pay a delinquency fee.
- (d) A license that is not renewed within three years after its expiration may not be renewed, restored, reinstated, or reissued thereafter; however, the former licensee may apply for and obtain a new license if he or she satisfies all of the following requirements:
- (1) No fact, circumstance, or condition exists that, if the license were issued, would justify its revocation or suspension.
 - (2) He or she submits an application for examination eligibility.
- (3) He or she takes and passes the current licensing examinations.
- (4) He or she submits the fees for examination eligibility and for initial license issuance.
- (5) He or she complies with the fingerprint requirements established by board regulation.

SEC. 26.

- *SEC. 41.* Section 4999.22 of the Business and Professions Code is amended to read:
- 4999.22. (a) Nothing in this chapter shall prevent qualified persons from doing work of a psychosocial nature consistent with
- 38 the standards and ethics of their respective professions. However,
- 39 these qualified persons shall not hold themselves out to the public
- 40 by any title or description of services incorporating the words

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1 "licensed professional clinical counselor" and shall not state that 2 they are licensed to practice professional clinical counseling, unless 3 they are otherwise licensed to provide professional clinical 4 counseling services.

- (b) Nothing in this chapter shall be construed to constrict, limit, or withdraw provisions of the Medical Practice Act, the Clinical Social Worker Practice Act, the Nursing Practice Act, the Psychology Licensing Law, or the Licensed Marriage and Family Therapist Act.
- (c) This chapter shall not apply to any priest, rabbi, or minister of the gospel of any religious denomination who performs counseling services as part of his or her pastoral or professional duties, or to any person who is admitted to practice law in this state, or who is licensed to practice medicine, who provides counseling services as part of his or her professional practice.
- (d) This chapter shall not apply to an employee of a governmental entity or a school, college, or university, or of an institution both nonprofit and charitable, if his or her practice is performed solely under the supervision of the entity, school, college, university, or institution by which he or she is employed, and if he or she performs those functions as part of the position for which he or she is employed.
- (e) All persons registered as interns or licensed under this chapter shall not be exempt from this chapter or the jurisdiction of the board.

SEC. 27.

- SEC. 42. Section 4999.32 of the Business and Professions Code is amended to read:
- 4999.32. (a) This section shall apply to applicants for examination eligibility or registration who begin graduate study before August 1, 2012, and complete that study on or before December 31, 2018. Those applicants may alternatively qualify under paragraph (2) of subdivision (a) of Section 4999.33.
- (b) To qualify for examination eligibility or registration, applicants shall possess a master's or doctoral degree that is counseling or psychotherapy in content and that meets the requirements of this section, obtained from an accredited or approved institution, as defined in Section 4999.12. For purposes of this subdivision, a degree is "counseling or psychotherapy in content" if it contains the supervised practicum or field study

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experience described in paragraph (3) of subdivision (c) and, except as provided in subdivision (d), the coursework in the core content areas listed in subparagraphs (A) to (I), inclusive, of paragraph (1) of subdivision (c).

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- (c) The degree described in subdivision (b) shall contain not less than 48 graduate semester or 72 graduate quarter units of instruction, which shall, except as provided in subdivision (d), include all of the following:
- (1) The equivalent of at least three semester units or four and one-half quarter units of graduate study in each of following core content areas:
- (A) Counseling and psychotherapeutic theories and techniques, including the counseling process in a multicultural society, an orientation to wellness and prevention, counseling theories to assist in selection of appropriate counseling interventions, models of counseling consistent with current professional research and practice, development of a personal model of counseling, and multidisciplinary responses to crises, emergencies, and disasters.
- (B) Human growth and development across the lifespan, including normal and abnormal behavior and an understanding of developmental crises, disability, psychopathology, and situational and environmental factors that affect both normal and abnormal behavior.
- (C) Career development theories and techniques, including career development decisionmaking models and interrelationships among and between work, family, and other life roles and factors, including the role of multicultural issues in career development.
- (D) Group counseling theories and techniques, including principles of group dynamics, group process components, developmental stage theories, therapeutic factors of group work, group leadership styles and approaches, pertinent research and literature, group counseling methods, and evaluation of effectiveness.
- (E) Assessment, appraisal, and testing of individuals, including basic concepts of standardized and nonstandardized testing and other assessment techniques, norm-referenced and criterion-referenced assessment, statistical concepts, social and cultural factors related to assessment and evaluation of individuals and groups, and ethical strategies for selecting, administering, and interpreting assessment instruments and techniques in counseling.

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(F) Multicultural counseling theories and techniques, including counselors' roles in developing cultural self-awareness, identity development, promoting cultural social justice, individual and community strategies for working with and advocating for diverse populations, and counselors' roles in eliminating biases and prejudices, and processes of intentional and unintentional oppression and discrimination.

- (G) Principles of the diagnostic process, including differential diagnosis, and the use of current diagnostic tools, such as the current edition of the Diagnostic and Statistical Manual, the impact of co-occurring substance use disorders or medical psychological disorders, established diagnostic criteria for mental or emotional disorders, and the treatment modalities and placement criteria within the continuum of care.
- (H) Research and evaluation, including studies that provide an understanding of research methods, statistical analysis, the use of research to inform evidence-based practice, the importance of research in advancing the profession of counseling, and statistical methods used in conducting research, needs assessment, and program evaluation.
- (I) Professional orientation, ethics, and law in counseling, including professional ethical standards and legal considerations, licensing law and process, regulatory laws that delineate the profession's scope of practice, counselor-client privilege, confidentiality, the client dangerous to self or others, treatment of minors with or without parental consent, relationship between practitioner's sense of self and human values, functions and relationships with other human service providers, strategies for collaboration, and advocacy processes needed to address institutional and social barriers that impede access, equity, and success for clients.
- (2) In addition to the course requirements described in paragraph (1), a minimum of 12 semester units or 18 quarter units of advanced coursework to develop knowledge of specific treatment issues, special populations, application of counseling constructs, assessment and treatment planning, clinical interventions, therapeutic relationships, psychopathology, or other clinical topics.
- (3) Not less than six semester units or nine quarter units of supervised practicum or field study experience, or the equivalent,

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1 in a clinical setting that provides a range of professional clinical counseling experience, including the following:

- (A) Applied psychotherapeutic techniques.
- 4 (B) Assessment.
- 5 (C) Diagnosis.

- (D) Prognosis.
- 7 (E) Treatment.
- 8 (F) Issues of development, adjustment, and maladjustment.
 - (G) Health and wellness promotion.
- 10 (H) Other recognized counseling interventions.
 - (I) A minimum of 150 hours of face-to-face supervised clinical experience counseling individuals, families, or groups.
 - (d) (1) An applicant whose degree is deficient in no more than two of the required areas of study listed in subparagraphs (A) to (I), inclusive, of paragraph (1) of subdivision (c) may satisfy those deficiencies by successfully completing post-master's or postdoctoral degree coursework at an accredited or approved institution, as defined in Section 4999.12.
 - (2) Coursework taken to meet deficiencies in the required areas of study listed in subparagraphs (A) to (I), inclusive, of paragraph (1) of subdivision (c) shall be the equivalent of three semester units or four and one-half quarter units of study.
 - (3) The board shall make the final determination as to whether a degree meets all requirements, including, but not limited to, course requirements, regardless of accreditation.
 - (e) In addition to the degree described in this section, or as part of that degree, an applicant shall complete the following coursework or training prior to registration as an intern:
 - (1) A minimum of 15 contact hours of instruction in alcoholism and other chemical substance abuse dependency, as specified by regulation.
 - (2) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25, and any regulations promulgated thereunder.
 - (3) A two semester unit or three quarter unit survey course in psychopharmacology.
 - (4) A minimum of 15 contact hours of instruction in spousal or partner abuse assessment, detection, and intervention strategies, including knowledge of community resources, cultural factors, and same gender abuse dynamics.

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(5) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28 and any regulations adopted thereunder.

- (6) A minimum of 18 contact hours of instruction in California law and professional ethics for professional clinical counselors that includes, but is not limited to, instruction in advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous clients, psychotherapist-client privilege, recordkeeping, client access to records, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, therapist disclosures to clients, and state and federal laws related to confidentiality of patient health information. When coursework in a master's or doctoral degree program is acquired to satisfy this requirement, it shall be considered as part of the 48 semester unit or 72 quarter unit requirement in subdivision (c).
- (7) A minimum of 10 contact hours of instruction in aging and long-term care, which may include, but is not limited to, the biological, social, and psychological aspects of aging. On and after January 1, 2012, this coursework shall include instruction on the assessment and reporting of, as well as treatment related to, elder and dependent adult abuse and neglect.
- (8) A minimum of 15 contact hours of instruction in crisis or trauma counseling, including multidisciplinary responses to crises, emergencies, or disasters, and brief, intermediate, and long-term approaches.
- (f) This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2019, deletes or extends that date.

SEC. 28.

SEC. 43. Section 4999.45 of the Business and Professions Code, as amended by Section 32 of Chapter 387 of the Statutes of 2011, is repealed.

36 SEC. 29.

37 SEC. 44. Section 4999.45 of the Business and Professions 38 Code, as added by Section 33 of Chapter 387 of the Statutes of 39 2011, is amended to read:

4999.45. (a) An intern employed under this chapter shall:

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(1) Not perform any duties, except for those services provided as a clinical counselor trainee, until registered as an intern.

- (2) Not be employed or volunteer in a private practice until registered as an intern.
- (3) Inform each client prior to performing any professional services that he or she is unlicensed and under supervision.
- (4) Renew annually for a maximum of five years after initial registration with the board.
- (b) When no further renewals are possible, an applicant may apply for and obtain a new intern registration if the applicant meets the educational requirements for registration in effect at the time of the application for a new intern registration and has passed the California law and ethics examination described in Section 4999.53. An applicant issued a subsequent intern registration pursuant to this subdivision may be employed or volunteer in any allowable work setting except private practice.
- SEC. 45. Section 4999.46 of the Business and Professions Code, as added by Section 35 of Chapter 387 of the Statutes of 2011, is amended to read:
- 499.46. (a) To qualify for the licensure examination specified by paragraph (2) of subdivision (a) of Section 4999.53, applicants shall complete clinical mental health experience under the general supervision of an approved supervisor as defined in Section 4999.12.
- (b) The experience shall include a minimum of 3,000 postdegree hours of supervised clinical mental health experience related to the practice of professional clinical counseling, performed over a period of not less than two years (104 weeks), which shall include:
 - (1) Not more than 40 hours in any seven consecutive days.
- (2) Not less than 1,750 hours of direct counseling with individuals or groups in a setting described in Section 4999.44 using a variety of psychotherapeutic techniques and recognized counseling interventions within the scope of practice of licensed professional clinical counselors.
- (3) Not more than 500 hours of experience providing group therapy or group counseling.
- (4) Not more than 250 hours of experience providing counseling or crisis counseling on the telephone.

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(5) Not less than 150 hours of clinical experience in a hospital or community mental health setting, as defined in Section 1820 of Title 16 of the California Code of Regulations.

- 4 (6) Not more than a combined total of 1,250 hours of experience 5 in the following related activities:
 - (A) Direct supervisor contact.
 - (B) Client centered advocacy.
 - (C) Not more than 250 hours of experience administering tests and evaluating psychological tests of clients, writing clinical reports, writing progress notes, or writing process notes.
 - (D) Not more than 250 hours of verified attendance at workshops, training sessions, or conferences directly related to professional clinical counseling that are approved by the applicant's supervisor.
 - (c) No hours of clinical mental health experience may be gained more than six years prior to the date the application for examination eligibility was filed.
 - (d) An applicant shall register with the board as an intern in order to be credited for postdegree hours of experience toward licensure. Postdegree hours of experience shall be credited toward licensure, provided that the applicant applies for intern registration within 90 days of the granting of the qualifying degree and is registered as an intern by the board.
 - (e) All applicants and interns shall be at all times under the supervision of a supervisor who shall be responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who shall be responsible to the board for compliance with all laws, rules, and regulations governing the practice of professional clinical counseling.
 - (f) Experience obtained under the supervision of a spouse or relative by blood or marriage shall not be credited toward the required hours of supervised experience. Experience obtained under the supervision of a supervisor with whom the applicant has had or currently has a personal, professional, or business relationship that undermines the authority or effectiveness of the supervision shall not be credited toward the required hours of supervised experience.

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(g) Supervision shall include at least one hour of direct supervisor contact in each week for which experience is credited in each work setting.

- (1) No more than five hours of supervision, whether individual or group, shall be credited during any single week.
- (2) An intern shall receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of face-to-face psychotherapy is performed in each setting in which experience is gained.
- (3) For purposes of this section, "one hour of direct supervisor contact" means one hour of face-to-face contact on an individual basis or two hours of face-to-face contact in a group of not more than eight persons in segments lasting no less than one continuous hour.
- (4) Notwithstanding paragraph (3), an intern working in a governmental entity, a school, a college, or a university, or an institution that is both nonprofit and charitable, may obtain the required weekly direct supervisor contact via two-way, real-time videoconferencing. The supervisor shall be responsible for ensuring that client confidentiality is upheld.
 - (h) This section shall become operative on January 1, 2013. SEC. 30.
- *SEC. 46.* Section 4999.57 of the Business and Professions Code is amended to read:
- 4999.57. (a) This section applies to a person who applies for examination eligibility or registration between January 1, 2011, and December 31, 2013, inclusive, who does not hold a license described in subdivision (a) of Section 4999.58.
- (b) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter, if the applicant complies with Section 4999.40, if applicable, and if the applicant has gained a minimum of 250 hours of supervised experience in direct counseling within California while registered as an intern with the board.
- (c) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, *and* if the applicant has completed the training or coursework required under subdivision (e) of Section 4999.32, which includes, in addition to

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> the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics for professional clinical counselors.

- (d) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:
- (1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.
- (2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.
 - (3) The applicant's degree otherwise complies with this section.
- (e) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

SEC. 31.

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- SEC. 47. Section 4999.58 of the Business and Professions Code is amended to read:
- 4999.58. (a) This section applies to a person who applies for examination eligibility between January 1, 2011, and December 31, 2013, inclusive, and who meets both of the following requirements:
- (1) At the time of application, holds a valid license as a professional clinical counselor, or other counseling license that allows the applicant to independently provide clinical mental health services, in another jurisdiction of the United States.
- (2) Has held the license described in paragraph (1) for at least two years immediately preceding the date of application.
- (b) The board may issue a license to a person described in subdivision (a) if all of the following requirements are satisfied:
- (1) The education and supervised experience requirements of the other jurisdiction are substantially the equivalent of this chapter, as described in subdivision (e) and in Section 4999.46.
- (2) The person complies with subdivision (b) of Section 4999.40, 40 if applicable.

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(3) The person successfully completes the examinations required by the board pursuant to paragraph (3) of subdivision (a) of Section 4999.50.

(4) The person pays the required fees.

- (c) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter. The board shall consider hours of experience obtained in another state during the six-year period immediately preceding the applicant's initial licensure by that state as a licensed professional clinical counselor.
- (d) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, *and* if the applicant has completed the training or coursework required under subdivision (e) of Section 4999.32, which includes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics for professional clinical counselors.
- (e) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:
- (1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.
- (2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.
 - (3) The applicant's degree otherwise complies with this section.
- (f) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

SEC. 32.

- *SEC. 48.* Section 4999.59 of the Business and Professions Code is amended to read:
- 4999.59. (a) This section applies to a person who applies for examination eligibility or registration between January 1, 2011,

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 and December 31, 2013, inclusive, who meets both of the following requirements:

- (1) At the time of application, holds a valid license described in paragraph (1) of subdivision (a) of Section 4999.58.
- (2) Has held the license described in paragraph (1) for less than two years immediately preceding the date of application.
- (b) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter, if the applicant complies with Section 4999.40, if applicable, and if the applicant has gained a minimum of 250 hours of supervised experience in direct counseling within California while registered as an intern with the board. The board shall consider hours of experience obtained in another state during the six-year period immediately preceding the applicant's initial licensure in that state as a professional clinical counselor.
- (c) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, *and* if the applicant has completed the training or coursework required under subdivision (e) of Section 4999.32, which includes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics for professional clinical counselors.
- (d) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:
- (1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.
- (2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.
 - (3) The applicant's degree otherwise complies with this section.

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(e) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

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- 4 SEC. 49. Section 4999.62 of the Business and Professions Code is amended to read:
 - 4999.62. (a) This section applies to persons who apply for examination eligibility or registration on or after January 1, 2014.
 - (b) For purposes of Sections 4999.60 and 4999.61, education is substantially equivalent if all of the following requirements are met:
 - (1) The degree is obtained from an accredited or approved institution, as defined in Section 4999.12, and consists of, at a minimum, 48 semester or 72 quarter units, including, but not limited to, both of the following:
 - (A) Six semester or nine quarter units of practicum, including, but not limited to, a minimum of 280 hours of face-to-face counseling.
 - (B) The required areas of study listed in subparagraphs (A) to (M), inclusive, of paragraph (1) of subdivision (c) of Section 4999.33.
 - (2) The applicant completes any units and course content requirements under Section 4999.33 not already completed in his or her education.
 - (3) The applicant completes credit level coursework from a degree-granting institution that provides all of the following:
 - (A) Instruction regarding the principles of mental health recovery-oriented care and methods of service delivery in recovery model practice environments.
 - (B) An understanding of various California cultures and the social and psychological implications of socioeconomic position.
 - (C) Structured meeting with various consumers and family members of consumers of mental health services to enhance understanding of their experience of mental illness, treatment, and recovery.
 - (D) Instruction in behavioral addiction and co-occurring substance abuse and mental health disorders, as specified in subparagraph (K) of paragraph (1) of subdivision (c) of Section 4999.33.
 - (4) The applicant completes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section

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4999.33, an 18-hour course in California law and professional ethics that includes, but is not limited to, instruction in advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous clients, psychotherapist-client privilege, recordkeeping, client access to records, the Health Insurance Portability and Accountability Act state and federal laws relating to confidentiality of patient health information, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to clients.

SEC. 50. Section 4999.76 of the Business and Professions Code is amended to read:

4999.76. (a) (1)—Except as provided in—paragraph (2) and subdivision (c), the board shall not renew any license pursuant to this chapter unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed not less than 36 hours of approved continuing education in or relevant to the field of professional clinical counseling in the preceding two years, as determined by the board.

- (2) Except as provided in subdivision (e), the board shall not renew a license issued pursuant to paragraph (1) of subdivision (a) of Section 4999.54 unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed not less than 18 hours of approved continuing education in or relevant to the field of professional clinical counseling in the preceding year, as determined by the board. This paragraph shall become inoperative on January 1, 2018.
- (b) The board shall have the right to audit the records of any applicant to verify the completion of the continuing education requirement. Applicants shall maintain records of completed continuing education coursework for a minimum of two years and shall make these records available to the board for auditing purposes upon request.
- (c) The board may establish exceptions from the continuing education requirement of this section for good cause, as defined by the board.
- 39 (d) The continuing education shall be obtained from one of the 40 following sources:

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(1) A school, college, or university that is accredited or approved, as defined in Section 4999.12. Nothing in this paragraph shall be construed as requiring coursework to be offered as part of a regular degree program.

- (2) Other continuing education providers, including, but not limited to, a professional clinical counseling association, a licensed health facility, a governmental entity, a continuing education unit of a four-year institution of higher learning that is accredited or approved, or a mental health professional association, approved by the board.
- (e) The board shall establish, by regulation, a procedure for approving providers of continuing education courses, and all providers of continuing education, as described in paragraphs (1) and (2) of subdivision (d), shall adhere to procedures established by the board. The board may revoke or deny the right of a provider to offer continuing education coursework pursuant to this section for failure to comply with the requirements of this section or any regulation adopted pursuant to this section.
- (f) Training, education, and coursework by approved providers shall incorporate one or more of the following:
- (1) Aspects of the discipline that are fundamental to the understanding or the practice of professional clinical counseling.
- (2) Significant recent developments in the discipline of professional clinical counseling.
- (3) Aspects of other disciplines that enhance the understanding or the practice of professional clinical counseling.
- (g) A system of continuing education for licensed professional clinical counselors shall include courses directly related to the diagnosis, assessment, and treatment of the client population being served.
- (h) The board shall, by regulation, fund the administration of this section through continuing education provider fees to be deposited in the Behavioral Sciences Fund. The fees related to the administration of this section shall be sufficient to meet, but shall not exceed, the costs of administering the corresponding provisions of this section. For the purposes of this subdivision, a provider of continuing education as described in paragraph (1) of subdivision (d) shall be deemed to be an approved provider.
- (i) The continuing education requirements of this section shall fully comply with the guidelines for mandatory continuing

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1 education established by the Department of Consumer Affairs 2 pursuant to Section 166.

SEC. 33.

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SEC. 51. Section 4999.90 of the Business and Professions Code is amended to read:

4999.90. The board may refuse to issue any registration or license, or may suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

- (a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter shall be deemed to be a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.
- (b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.
- (c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022, or any alcoholic beverage to the extent, or in a manner, as to be

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dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license. The board shall deny an application for a registration or license or revoke the license or registration of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing licensed professional clinical counseling services.

- (d) Gross negligence or incompetence in the performance of licensed professional clinical counseling services.
- (e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.
- (f) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.
- (g) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee or registrant, allowing any other person to use his or her license or registration.
- (h) Aiding or abetting, or employing, directly or indirectly, any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.
- (i) Intentionally or recklessly causing physical or emotional harm to any client.
- (j) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.
- (k) Engaging in sexual relations with a client, or a former client within two years following termination of therapy, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed professional clinical counselor.

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(*l*) Performing, or holding oneself out as being able to perform, or offering to perform, or permitting any trainee, applicant, or registrant under supervision to perform, any professional services beyond the scope of the license authorized by this chapter.

- (m) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client which is obtained from tests or other means.
- (n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.
- (o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional clinical counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (n).
- (p) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.
- (q) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device.
- (r) Any conduct in the supervision of a registered intern, associate clinical social worker, or clinical counselor trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.
- (s) Performing or holding oneself out as being able to perform professional services beyond the scope of one's competence, as established by one's education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.
- (t) Permitting a clinical counselor trainee or intern under one's supervision or control to perform, or permitting the clinical

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counselor trainee or intern to hold himself or herself out as competent to perform, professional services beyond the clinical counselor trainee's or intern's level of education, training, or experience.

- (u) The violation of any statute or regulation of the standards of the profession, and the nature of the services being rendered, governing the gaining and supervision of experience required by this chapter.
- (v) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.
- (w) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.
- (x) Failing to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.
 - (y) Repeated acts of negligence.

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- (z) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.
- (2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.
- (aa) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of an examination as described in Section 123.
- (ab) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a professional clinical counselor, clinical social worker, educational psychologist, professional clinical counselor, or marriage and family therapist.

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1 (ac) Failing to comply with the procedures set forth in Section 2 2290.5 when delivering health care via telemedicine.

- (ad) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code. SEC. 34.
- SEC. 52. Section 4999.106 of the Business and Professions Code is amended to read:
- 4999.106. A license that is not renewed within three years after its expiration may not be renewed, restored, reinstated, or reissued, except that a former licensee may apply for and obtain a new license if he or she complies with all of the following:
- (a) No fact, circumstance, or condition exists that, if the license were issued, would justify its revocation or suspension.
- (b) He or she takes and passes the current examinations required for licensing.
 - (c) He or she submits an application for initial licensure.
- (d) He or she meets the requirements pursuant to Section 4999.51.
 - SEC. 35.

- 20 SEC. 53. Section 4999.120 of the Business and Professions 21 Code is amended to read:
 - 4999.120. The board shall assess fees for the application for and the issuance and renewal of licenses and for the registration of interns to cover administrative and operating expenses of the board related to this chapter. Fees assessed pursuant to this section shall not exceed the following:
 - (a) The fee for the application for examination eligibility shall be up to two hundred fifty dollars (\$250).
 - (b) The fee for the application for intern registration shall be up to one hundred fifty dollars (\$150).
 - (c) The fee for the application for licensure shall be up to one hundred eighty dollars (\$180).
 - (d) The fee for the board-administered clinical examination, if the board chooses to adopt this examination in regulations, shall be up to two hundred fifty dollars (\$250).
 - (e) The fee for the law and ethics examination shall be up to one hundred fifty dollars (\$150).
- 38 (f) The fee for the examination described in subdivision (b) of 39 Section 4999.54 shall be up to one hundred dollars (\$100).

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(g) The fee for the issuance of a license shall be up to two hundred fifty dollars (\$250).

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- (h) The fee for annual renewal of an intern registration shall be up to one hundred fifty dollars (\$150).
- (i) The fee for two-year renewal of licenses shall be up to two hundred fifty dollars (\$250).
- (j) The fee for issuance of a retired license shall be forty dollars (\$40).
- (k) The fee for rescoring an examination shall be twenty dollars 10 (\$20).
 - (1) The fee for issuance of a replacement license or registration shall be twenty dollars (\$20).
 - (m) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars (\$25).
 - SEC. 36. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
 - SEC. 54. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.
 - However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: SB 1575 VERSION: Amended April 16, 2012

AUTHOR: Senate Committee on Business, Professions and Economic Development

COMMITTEE RECOMMENDATION: SUPPORT

SUBJECT: Professions and Vocations (Omnibus)

Affected Amends / Adds various sections of the Business and Professions Code

Sections: related to Healing Arts, including:

Section 144.5 - Records

Section 4209 – Pharmacist Exam Applications; Certification of Intern Hours Section 4300.1 – Board jurisdiction to proceed with discipline on a license

Current Status: 4/23/12 – Do Pass from SEN Committee on Business, Professions and

Economic Development. Referred to Senate Appropriations.

EXISTING LAW:

 Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.

- 2. Provides for the licensing, oversight and regulation of the practice of pharmacy by the Board of Pharmacy (Business and Professions Code Section 4000 et seq.)
 - a. Authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct.
 - b. Requires a pharmacist exam applicant who has been licensed as a pharmacist in another state for at least one year, as specified, to submit certification of licensure from the other state to satisfy the required 1,500 hours of intern experience required to sit for the exam.

THIS BILL:

1. Adds Section 144.5 to the Business and Professions Code to allow the board to request – and require a local or state agency to provide – certified records of arrests, convictions and other related documentation needed to complete an applicant or licensee investigation. [SECTION 1., p. 7]

- 2. Amends Section 4209 related to pharmacist exam applicants to [SEC. 20, p. 22]
 - **a.** Specify that an intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours; and,
 - **b.** For the pharmacist exam applicant that has been licensed as a pharmacist in another state for at least one year, that he or she may submit certification of licensure from the other state to satisfy the 1,500 hours of intern experience required, so long as the applicant has obtained *a minimum of 900 hours* of pharmacy practice experience in a pharmacy as a pharmacist.
- 3. Adds Section 4300.1 to the Business and Professions Code to ensure the board's jurisdiction to commence or proceed with an investigation of, or action or disciplinary action against, a license or render a decision to suspend or revoke a license even if that license has been cancelled, forfeited, suspended, surrendered, placed on retired status, etc. [SEC. 21, p. 23]

COMMENTS:

October 2011 – The board approved the omnibus provisions to amend Section 4209 January 2012 – The board approved omnibus provisions to add Section 4300.1

HISTORY:

Date Action
2012

Apr. 16 From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.

Apr. 11 Set for hearing April 23.

Mar. 26 Referred to Com. on B., P. & E.D.

Mar. 13 From printer. May be acted upon on or after April 12.

Mar. 12 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Attachment 2

Introduced by Senator Price

February 23, 2012

An act to amend Sections 4001, 4003, 8000, and 8005, 8027, 8030.2, and 8030.5 of the Business and Professions Code, relating to professions, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, as amended, Price. Professions: pharmacists—and, court reporters: reporters, and Transcript Reimbursement Fund: sunset dates.

(1) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law authorizes the board to appoint an executive officer. Under existing law, the board and its authority to appoint an executive officer will be repealed on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of the California State Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

(2) Existing law provides for the licensure and regulation of court reporters by the Court Reporters Board of California within the Department of Consumer Affairs. Existing law authorizes this board to appoint an executive officer and committees as necessary. Existing law repeals these provisions on January 1, 2013.

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This bill would extend the operation of these provisions until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

Existing law requires, until January 1, 2013, certain fees and revenues collected by the board to be deposited into the Transcript Reimbursement Fund, to be available to provide reimbursement for the cost of providing shorthand reporting services to low-income litigants in civil cases. Existing law authorizes, until January 1, 2013, low-income persons appearing pro se to apply for funds from the Transcript Reimbursement Fund, subject to specified requirements and limitations. Existing law requires the board, until January 1, 2013, to publicize the availability of the fund to prospective applicants. Existing law requires the unencumbered funds remaining in the Transcript Reimbursement Fund as of January 1, 2013, to be transferred to the Court Reporters' Fund.

This bill would extend the operation of these provisions until January 1, 2017, and would make a technical change to these provisions. By extending the operation of the Transcript Reimbursement Fund, which is a continuously appropriated fund, the bill would make an appropriation.

Vote: majority. Appropriation: no-yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 4001 of the Business and Professions Code is amended to read:
- 4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of members.
 - (b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

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14 (c) At least five of the seven pharmacist appointees to the board 15 shall be pharmacists who are actively engaged in the practice of -3- SB 1237

pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

- (d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.
- (e) Each member of the board shall receive a per diem and expenses as provided in Section 103.
- (f) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.
- SEC. 2. Section 4003 of the Business and Professions Code is amended to read:
- 4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.
- (b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

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(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

- (d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.
- (e) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.
- SEC. 3. Section 8000 of the Business and Professions Code is amended to read:
- 8000. (a) There is in the Department of Consumer Affairs a Court Reporters Board of California, which consists of five members, three of whom shall be public members and two of whom shall be holders of certificates issued under this chapter who have been actively engaged as shorthand reporters within this state for at least five years immediately preceding their appointment.
- (b) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.
- (c) Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.
- SEC. 4. Section 8005 of the Business and Professions Code is amended to read:
- 8005. The Court Reporters Board of California is charged with the executive functions necessary for effectuating the purposes of this chapter. It may appoint committees as it deems necessary or proper. The board may appoint, prescribe the duties, and fix the salary of an executive officer. Except as provided by Section 159.5, the board may also employ other employees as may be necessary, subject to civil service and other provisions of law.
- This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.
- SEC. 5. Section 8027 of the Business and Professions Code is amended to read:

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8027. (a) As used in this section, "school" means a court reporter training program or an institution that provides a course of instruction approved by the board and the Bureau for Private Postsecondary and Vocational Education, is a public school in this state, or is accredited by the Western Association of Schools and Colleges.

- (b) A court reporting school shall be primarily organized to train students for the practice of shorthand reporting, as defined in Sections 8016 and 8017. Its educational program shall be on the postsecondary or collegiate level. It shall be legally organized and authorized to conduct its program under all applicable laws of the state, and shall conform to and offer all components of the minimum prescribed course of study established by the board. Its records shall be kept and shall be maintained in a manner to render them safe from theft, fire, or other loss. The records shall indicate positive daily and clock-hour attendance of each student for all classes, apprenticeship and graduation reports, high school transcripts or the equivalent or self-certification of high school graduation or the equivalent, transcripts of other education, and student progress to date, including all progress and counseling reports.
- (c) Any school intending to offer a program in court reporting shall notify the board within 30 days of the date on which it provides notice to, or seeks approval from, the State Department of Education, the Bureau for Private Postsecondary and Vocational Education, the Office of the Chancellor of the California Community Colleges, or the Western Association of Schools and Colleges, whichever is applicable. The board shall review the proposed curriculum and provide the school tentative approval, or notice of denial, within 60 days of receipt of the notice. The school shall apply for provisional recognition pursuant to subdivision (d) within no more than one year from the date it begins offering court reporting classes.
- (d) The board may grant provisional recognition to a new court reporting school upon satisfactory evidence that it has met all of the provisions of subdivision (b) and this subdivision. Recognition may be granted by the board to a provisionally recognized school after it has been in continuous operation for a period of no less than three consecutive years from the date provisional recognition was granted, during which period the school shall provide

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satisfactory evidence that at least one person has successfully completed the entire course of study established by the board and complied with the provisions of Section 8020, and has been issued a certificate to practice shorthand reporting as defined in Sections 8016 and 8017. The board may, for good cause shown, extend the three-year provisional recognition period for not more than one year. Failure to meet the provisions and terms of this section shall require the board to deny recognition. Once granted, recognition may be withdrawn by the board for failure to comply with all applicable laws and regulations.

- (e) Application for recognition of a court reporting school shall be made upon a form prescribed by the board and shall be accompanied by all evidence, statements, or documents requested. Each branch, extension center, or off-campus facility requires separate application.
- (f) All recognized and provisionally recognized court reporting schools shall notify the board of any change in school name, address, telephone number, responsible court reporting program manager, owner of private schools, and the effective date thereof, within 30 days of the change. All of these notifications shall be made in writing.
- (g) A school shall notify the board in writing immediately of the discontinuance or pending discontinuance of its court reporting program or any of the program's components. Within two years of the date this notice is sent to the board, the school shall discontinue its court reporting program in its entirety. The board may, for good cause shown, grant not more than two one-year extensions of this period to a school. If a student is to be enrolled after this notice is sent to the board, a school shall disclose to the student the fact of the discontinuance or pending discontinuance of its court reporting program or any of its program components.
- (h) The board shall maintain a roster of currently recognized and provisionally recognized court reporting schools, including, but not limited to, the name, address, telephone number, and the name of the responsible court reporting program manager of each school.
- (i) The board shall maintain statistics that display the number and passing percentage of all first-time examinees, including, but not limited to, those qualified by each recognized or provisionally

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recognized school and those first-time examinees qualified by other methods as defined in Section 8020.

- (j) Inspections and investigations shall be conducted by the board as necessary to carry out this section, including, but not limited to, unannounced site visits.
- (k) All recognized and provisionally recognized schools shall print in their school or course catalog the name, address, and telephone number of the board. At a minimum, the information shall be in 8-point bold type and include the following statement:

"IN ORDER FOR A PERSON TO QUALIFY FROM A SCHOOL TO TAKE THE STATE LICENSING EXAMINATION, THE PERSON SHALL COMPLETE A PROGRAM AT A RECOGNIZED SCHOOL. FOR INFORMATION CONCERNING THE MINIMUM REQUIREMENTS THAT A COURT REPORTING PROGRAM MUST MEET IN ORDER TO BE RECOGNIZED, CONTACT: THE COURT REPORTERS BOARD OF CALIFORNIA; (ADDRESS); (TELEPHONE NUMBER)."

(*l*) Each court reporting school shall file with the board, not later than June 30 of each year, a current school catalog that shows all course offerings and staff, and for private schools, the owner, except that where there have been no changes to the catalog within the previous year, no catalog need be sent. In addition, each school shall also file with the board a statement certifying whether the school is in compliance with all statutes and the rules and regulations of the board, signed by the responsible court reporting program manager.

(m) A school offering court reporting shall not make any written or verbal claims of employment opportunities or potential earnings unless those claims are based on verified data and reflect current employment conditions.

(n) If a school offers a course of instruction that exceeds the board's minimum requirements, the school shall disclose orally and in writing the board's minimum requirements and how the course of instruction differs from those criteria. The school shall make this disclosure before a prospective student executes an agreement obligating that person to pay any money to the school

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for the course of instruction. The school shall also make this disclosure to all students enrolled on January 1, 2002.

- (o) Private and public schools shall provide each prospective student with all of the following and have the prospective student sign a document that shall become part of that individual's permanent record, acknowledging receipt of each item:
- (1) A student consumer information brochure published by the board.
- (2) A list of the school's graduation requirements, including the number of tests, the pass point of each test, the speed of each test, and the type of test, such as jury charge or literary.
- (3) A list of requirements to qualify for the state-certified shorthand reporter licensing examination, including the number of tests, the pass point of each test, the speed of each test, and the type of test, such as jury charge or literary, if different than those requirements listed in paragraph (2).
- (4) A copy of the school's board-approved benchmarks for satisfactory progress as identified in subdivision (u).
- (5) A report showing the number of students from the school who qualified for each of the certified shorthand reporter licensing examinations within the preceding two years, the number of those students that passed each examination, the time, as of the date of qualification, that each student was enrolled in court reporting school, and the placement rate for all students that passed each examination.
- (6) On and after January 1, 2005, the school shall also provide to prospective students the number of hours each currently enrolled student who has qualified to take the next licensing test, exclusive of transfer students, has attended court reporting classes.
- (p) All enrolled students shall have the information in subdivisions (n) and (o) on file no later than June 30, 2005.
- (q) Public schools shall provide the information in subdivisions (n) and (o) to each new student the first day he or she attends theory or machine speed class, if it was not provided previously.
- (r) Each enrolled student shall be provided written notification of any change in qualification or graduation requirements that is being implemented due to the requirements of any one of the school's oversight agencies. This notice shall be provided to each affected student at least 30 days before the effective date of the change and shall state the new requirement and the name, address,

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and telephone number of the agency that is requiring it of the school. Each student shall initial and date a document acknowledging receipt of that information and that document, or a copy thereof, shall be made part of the student's permanent file.

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- (s) Schools shall make available a comprehensive final examination in each academic subject to any student desiring to challenge an academic class in order to obtain credit towards certification for the state licensing examination. The points required to pass a challenge examination shall not be higher than the minimum points required of other students completing the academic class.
- (t) An individual serving as a teacher, instructor, or reader shall meet the qualifications specified by regulation for his or her position.
- (u) Each school shall provide a substitute teacher or instructor for any class for which the teacher or instructor is absent for two consecutive days or more.
- (v) The board has the authority to approve or disapprove benchmarks for satisfactory progress which each school shall develop for its court reporting program. Schools shall use only board-approved benchmarks to comply with the provisions of paragraph (4) of subdivision (0) and subdivision (u).
- (w) Each school shall counsel each student a minimum of one time within each 12-month period to identify the level of attendance and progress, and the prognosis for completing the requirements to become eligible to sit for the state licensing examination. If the student has not progressed in accordance with the board-approved benchmarks for that school, the student shall be counseled a minimum of one additional time within that same 12-month period.
- (x) The school shall provide to the board, for each student qualifying through the school as eligible to sit for the state licensing examination, the number of hours the student attended court reporting classes, both academic and machine speed classes, including theory.
- (y) The pass rate of first-time examination takers for each school offering court reporting shall meet or exceed the average pass rate of all first-time test takers for a majority of examinations given for the preceding three years. Failure to do so shall require the board to conduct a review of the program. In addition, the board may place the school on probation and may withdraw recognition

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if the school continues to place below the above-described standard on the two examinations that follow the three-year period.

- (z) A school shall not require more than one 10-minute qualifying examination, as defined in the regulations of the board, for a student to be eligible to sit for the state certification examination.
- (aa) A school shall provide the board the actual number of hours of attendance for each applicant the school qualifies for the state licensing examination.
- (ab) The board shall, by December 1, 2001, do the following by regulation as necessary:
- (1) Establish the format that shall be used by schools to report tracking of all attendance hours and actual timeframes for completed coursework.
- (2) Require schools to provide a minimum of 10 hours of live dictation class each school week for every full-time student.
- (3) Require schools to provide students with the opportunity to read back from their stenographic notes a minimum of one time each day to his or her instructor.
- (4) Require schools to provide students with the opportunity to practice with a school-approved speed-building audio recording, or other assigned material, a minimum of one hour per day after school hours as a homework assignment and provide the notes from this audio recording to their instructor the following day for review.
- (5) Develop standardization of policies on the use and administration of qualifier examinations by schools.
- (6) Define qualifier examination as follows: the qualifier examination shall consist of 4-voice testimony of 10-minute duration at 200 words per minute, graded at 97.5 percent accuracy, and in accordance with the guidelines followed by the board. Schools shall be required to date and number each qualifier and announce the date and number to the students at the time of administering the qualifier. All qualifiers shall indicate the actual dictation time of the test and the school shall catalog and maintain the qualifier for a period of not less than three years for the purpose of inspection by the board.
- (7) Require schools to develop a program to provide students with the opportunity to interact with professional court reporters

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to provide skill support, mentoring, or counseling that they can document at least quarterly.

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- (8) Define qualifications and educational requirements required of instructors and readers that read test material and qualifiers.
- (ac) The board shall adopt regulations to implement the requirements of this section not later than September 1, 2002.
- (ad) The board may recover costs for any additional expenses incurred under the enactment amending this section in the 2001–02 Regular Session of the Legislature pursuant to its fee authority in Section 8031.
- SEC. 6. Section 8030.2 of the Business and Professions Code is amended to read:
- (a) To provide shorthand reporting services to low-income litigants in civil cases, who are unable to otherwise afford those services, funds generated by fees received by the board pursuant to subdivision (c) of Section 8031 in excess of funds needed to support the board's operating budget for the fiscal year in which a transfer described below is made shall be used by the board for the purpose of establishing and maintaining a Transcript Reimbursement Fund. The Transcript Reimbursement Fund shall be established by a transfer of funds from the Court Reporters' Fund in the amount of three hundred thousand dollars (\$300,000) at the beginning of each fiscal year. Notwithstanding any other provision of this article, a transfer to the Transcript Reimbursement Fund in excess of the fund balance established at the beginning of each fiscal year shall not be made by the board if the transfer will result in the reduction of the balance of the Court Reporters' Fund to an amount less than six months' operating budget.
- (b) All moneys held in the Court Reporters' Fund on the effective date of this section in excess of the board's operating budget for the 1996–97 fiscal year shall be used as provided in subdivision (a).
- (c) Refunds and unexpended funds that are anticipated to remain in the Transcript Reimbursement Fund at the end of the fiscal year shall be considered by the board in establishing the fee assessment pursuant to Section 8031 so that the assessment shall maintain the level of funding for the Transcript Reimbursement Fund, as specified in subdivision (a), in the following fiscal year.
- (d) The Transcript Reimbursement Fund is hereby created in the State Treasury. Notwithstanding Section 13340 of the

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Government Code, moneys in the Transcript Reimbursement Fund are continuously appropriated for the purposes of this chapter.

- (e) (1) Applicants, including applicants pursuant to Section 8030.5, who have been reimbursed pursuant to this chapter for services provided to litigants and who are awarded court costs or attorney's fees by judgment or by settlement agreement shall refund the full amount of that reimbursement to the fund within 90 days of receipt of the award or settlement.
- (2) An applicant pursuant to Section 8030.5 who has been reimbursed for services provided to litigants under this chapter shall refund the full amount reimbursed if a court orders the applicant's fee waiver withdrawn or denied retroactively pursuant to Section 68636 of the Government Code, within 90 days of the court's order withdrawing or denying the fee waiver.
- (f) Subject to the limitations of this chapter, the board shall maintain the fund at a level that is sufficient to pay all qualified claims. To accomplish this objective, the board shall utilize all refunds, unexpended funds, fees, and any other moneys received by the board.
- (g) Notwithstanding Section 16346 of the Government Code, all unencumbered funds remaining in the Transcript Reimbursement Fund as of January 1,—2013, 2017, shall be transferred to the Court Reporters' Fund.
- (h) This section shall remain in effect only until January 1, 2013, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, 2017, deletes or extends that date.
- SEC. 7. Section 8030.5 of the Business and Professions Code is amended to read:
- 8030.5. (a) Notwithstanding subdivision (e) of Section 8030.4, as used in this chapter the term "applicant" also means an indigent person, as defined in subdivision (f) of Section 8030.4, appearing pro se to represent himself or herself at any stage of the case and applying to receive funds from the Transcript Reimbursement Fund established by this chapter.
- (b) Notwithstanding Section 8030.6, total disbursements to cover the cost of providing transcripts to all applicants pursuant to this section shall not exceed thirty thousand dollars (\$30,000) annually and shall not exceed one thousand five hundred dollars (\$1,500) per case.

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(c) The board shall provide a report to the Senate and Assembly Committees on Judiciary by March 1, 2012, that includes a summary of the expenditures and claims relating to this article, including the initial fund balance as of January 1, 2011; all funds received, including the amount of, and reason for, any refunds pursuant to subdivision (e) of Section 8030.2; all claims received, including the type of case, court involved, service for which reimbursement was sought, amount paid, and amount denied, if any, and the reason for denial; and all administrative fees. This report shall be provided using existing resources.

- (d) The Legislature finds and declares that there are funds available for indigent pro se parties under this article only because the Transcript Reimbursement Fund has not been fully utilized in recent years by the eligible applicants for whom its use has been intended, despite the evident financial need among legal services organizations and pro bono attorneys. Accordingly, the board shall, using existing resources, undertake further efforts to publicize the availability of the Transcript Reimbursement Fund to prospective applicants, as defined in subdivision (e) of Section 8030.4, through appropriate entities serving these applicants, including the State Bar of California, the California Commission on Access to Justice, and the Legal Aid Association of California. These efforts shall be described in the report required by subdivision (c).
- (e) This section shall remain in effect only until January 1, 2013, 2017, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2013, 2017, deletes or extends that date.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NO.: SB 1237 VERSION: [A] April 16, 2012

AUTHOR: Price Committee

Recommendation:

SUBJECT: Sunset Review

Affected Sections: Amend Sections 4001 and 4003 of the Business and Professions Code (B&PC) related to the Board of Pharmacy. The measure also amends B&PC Sections 8000 and 8005 and other provisions related to the sunset of the Court Reporters Board of California.

CURRENT STATUS:

4/23/2012 – Do pass from SEN Committee on Business, Professions and Economic Development.

Referred to Senate Appropriations

EXISTING LAW:

- 1. Business and Professions Code Section 4001 sets forth the structure composure of the Board of Pharmacy, specifies terms of appointment, provides for board member per diem, etc. Existing law "sunsets" the Board of Pharmacy and its authority on January 1, 2013.
- 2. Business and Professions Code Section 4003 sets forth provisions related to the appointment of an Executive Officer (EO) of the board to include compensation and reimbursement of necessary expenses. This section further specifies duties of the EO related to records and revenue. Existing law "sunsets" these provisions on January 1, 2013.

AS AMENDED THIS BILL WOULD:

- 1. Amend B&PC Sections 4001 and 4003 to extend the operation of the Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.
- 2. This measure also amends sections 8000, et seq. related to the Court Reporters Board of California to extend the sunset of that board.

COMMENTS:

In November 2011, the Board provided its "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board's public website. The board last underwent sunset review in 2002.

http://www.pharmacy.ca.gov/publications/sunset_2011.pdf

On February 23, 2012, Senator Current Price, Chair of the Senate Committee on Business, Professions and Economic Development introduced SB 1237 to extend the board's authority to 2017. The bill would also extend the sunset of the Court Reporters Board. On April 16, 2012, the bill was amended to include additional amendments related to the Court Reporters Board Transcript Reimbursement Fund.

The Senate Committee on Business, Professions and Economic Development held an oversight hearing on March 19, 2012, at which Board President Stan Weisser and Executive Officer Virginia (Giny) Herold testified on a variety of issues, including the following topics:

- Effectiveness of the Board's Substance Abuse Recovery Program
- Drug Diversion and Prescription Monitoring Program (CURES)
- E-Pedigree
- Implementation of Patient-Centered Prescription Label Requirements
- Drug Take-Back and reuse Program

COMMITTEE RECOMMENDATION:

The Legislation and Regulation Committee met on April 24, 2012 and recommends that the Board **SUPPORT** SB 1237.

Introduced by Senator Simitian

February 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer

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of the county, as prescribed. This bill would also authorize a primary eare clinic dispensary, as defined, specified primary care clinics and pharmacies to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its-intent, intent and prohibit the pharmacy or clinic from participating until-and require the county board of supervisors or public health officer to approve the pharmacy or clinic health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care facilities, as specified, to donate unused medications to the program. This bill would authorize medication under the program to be transferred to another participating pharmacy or primary care clinic. This bill would also make other conforming changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 150201 of the Health and Safety Code is amended to read:
- 3 150201. (a) For purposes of this division, "medication"
- 4 150201. For purposes of this division:
- 5 (a) "Eligible entity" means all of the following:
- 6 (1) A licensed pharmacy, as defined in subdivision (a) of Section 7 4037 of the Business and Professions Code, that is county owned 8 or that contracts with the county pursuant to this division.
- 9 (2) A licensed pharmacy, as defined in subdivision (a) of Section 10 4037 of the Business and Professions Code, that is owned and 11 operated by a licensed primary care clinic, as defined in Section 12 1204.
- 13 (3) A licensed primary care clinic, as defined in Section 1204, 14 that is licensed to administer and dispense drugs pursuant to

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subparagraph (A) of paragraph (1) of subdivision (a) of Section
 4180 of the Business and Professions Code.

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- (b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.
- (b) For purposes of this division, "primary care clinic dispensary" means a licensed primary care clinic, as defined in Section 1204, that is licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code.
- (c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.
- SEC. 2. Section 150202 of the Health and Safety Code is amended to read:
- 150202. Notwithstanding any other provision of law, the following health and care facilities may donate unused medications under a program established pursuant to this division:
- (a) A licensed general acute care hospital, as defined in Section 1250.
- 22 (b) A licensed acute psychiatric hospital, as defined in Section 23 1250.
 - (c) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.
- 27 (d) A licensed intermediate care facility, as defined in Section 28 1250.
- 29 (e) A licensed intermediate care facility/developmentally 30 disabled-habilitative facility, as defined in Section 1250.
- 31 (f) A licensed intermediate care facility/developmentally 32 disabled-nursing facility, as defined in Section 1250.
- 33 (g) A licensed correctional treatment center, as defined in 34 Section 1250.
- 35 (h) A licensed psychiatric health facility, as defined in Section 36 1250.2.
- 37 (i) A licensed chemical dependency recovery hospital, as defined 38 in Section 1250.3.
- 39 (j) A licensed residential care facility for the elderly, as defined 40 in Section 1569.2.

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(k) A licensed residential care facility for persons with chronic, life-threatening illness, as defined in Section 1568.01.

- (l) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.
- SEC. 3. Section 150204 of the Health and Safety Code is amended to read:
- 150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as delegated by the county board of supervisors, a repository and distribution program for purposes of this division.
- (2) Only a pharmacy that is county-owned or that contracts with the county pursuant to this division, or a primary care clinic dispensary, as defined in subdivision (b) of Section 150201, is an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.
- (3) An eligible pharmacy or primary care clinic dispensary entity that seeks to participate in the program shall inform the county health department in writing of its intent to participate in the program. An eligible pharmacy or primary care clinic dispensary entity may not participate in the program-unless it is approved by the county board of supervisors or the public health officer of the county until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.
- (4) (A) A participating pharmacy or primary care clinic dispensary entity shall disclose to the county health department the name and location of the source of all donated medication it receives.
- (B) A participating primary care clinic dispensary primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the licensed physician to who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division.
- (C) The county board of supervisors or public health officer of 38 the county shall, upon request, make available to the California State Board of Pharmacy the information in this paragraph.

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(5) The county board of supervisors, the public health officer of the county, and the *California* State Board of Pharmacy may prohibit a pharmacy or primary care clinic dispensary an eligible or participating entity from participating in the program if the pharmacy or primary care clinic dispensary the entity does not comply with the provisions of the program, pursuant to this division.

- (b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:
- (1) Establishing eligibility for medically indigent patients who may participate in the program.
- (2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.
- (3) Developing a formulary of medications appropriate for the repository and distribution program.
- (4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy or primary care clinic dispensary participating entity.
- (5) Ensuring the privacy of individuals for whom the medication was originally prescribed.
- (c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:
 - (1) The medication shall not be a controlled substance.
- (2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.
- (3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of staff of the health or care facility, as described in Section 150202.
- (d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed.

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Medication donated in opened containers shall not be dispensed by the repository and distribution program.

- (e) A pharmacist or physician shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.
- (f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.
- (g) Medication that is donated to the repository and distribution program shall be handled in the following ways:
 - (1) Dispensed to an eligible patient.
 - (2) Destroyed.

- (3) Returned to a reverse distributor.
- (4) Transferred to another participating pharmacy or primary eare elinic dispensary entity to be dispensed to eligible patients pursuant to this division.
- (h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.
- (i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.
- (j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's or primary care clinic dispensary's participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.
- (k) The pharmacy or primary care clinic dispensary *A* participating entity shall keep complete records of the acquisition and disposition of medication donated to, transferred, and dispensed under the repository and distribution program. These records shall

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be kept separate from the pharmacy's or primary care clinic dispensary's participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

- (*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.
- (m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health—and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.
- (n) Notwithstanding any other provision of law, a participating eounty-owned or county-contracted pharmacy or primary care elinic dispensary entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.
- SEC. 4. Section 150205 of the Health and Safety Code is amended to read:
- 150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:
- (a) A prescription drug manufacturer, wholesaler, governmental entity, county-owned or county-contracted licensed pharmacy, or primary care clinic dispensary participating entity.
- (b) A pharmacist or health care professional who accepts or dispenses prescription drugs.
- (c) A health or care facility, as described in Section 150202.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NO.: SB 1329 VERSION: [A] Mar. 29, 2012

AUTHOR: Simitian Committee Support if Amended Recommendation:

SUBJECT: Surplus Medication Collection and Distribution

Affected Sections: Health & Safety Code Sections 150201, 150202, 150204 and 150205

Division 116. Surplus Medication Collection and Distribution

(§§ 150200-150207)

BILL STATUS:

April 12, 2012 – Passed out of SEN Committee on Health and Re-Referred to SEN Com. on Business, Professions and Economic Development.

May 7, 2012 – Set for Hearing in SEN Committee on Business, Professions and Economic Development

EXISTING LAW:

Under existing ¹law, a county may voluntarily establish a Surplus Medication Collection and Distribution (SMCD) Program through a county-owned pharmacy or a pharmacy that contracts with the county for this purpose. Counties that elect to operate a program by ordinance of the County Board of Supervisors must establish criteria to determine who is eligible to receive drugs from the program; develop a formulary of medications appropriate for the program; ensure the privacy of individuals for whom the medication was originally prescribed; and ensure the safe storage and management of medications that are collected and dispensed under the program. No controlled drugs may be donated, and a pharmacist or physician and surgeon must dispense the medications to eligible patients.

Existing Pharmacy Law provides for the licensure and regulation of pharmacies, pharmacists, wholesalers of dangerous drugs or devices, and other individuals and entities.

THIS BILL WOULD:

- Also allow a county Public Health Officer to establish a Surplus Medication Collection and Distribution Program in a county.
- Expand the types of facilities/entities that may donate surplus medications to a SMCD Program, to include ²residential care facilities and ³mental health rehabilitation centers.
- Allow for the transfer of donated surplus medications between SMCD programs.
- Require that eligible programs disclose specified information to the county and that, upon request, make that information available to the board.
- Allow a physician to determine if donated medications meet specified standards, and to adhere to standard pharmacy practices when dispensing medications.

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¹ Division 116 of the Health and Safety Code, Sections 150200-150207

² Licensed by the Department of Social Services

³ Licensed by the Department of Mental Health, Welfare and Institutions Code § 5675

Authorize the Board of Pharmacy to prohibit an entity from participating in a SMCD program.

FOR DISCUSSION:

Patient Drugs – This measure is silent on the patient's ownership of their drugs.

In various care settings, and with certain exceptions (i.e., such as a drug being returned for a pharmacy for credit for a Medicare and Medicaid patient) – once a drug is dispensed to a patient, the patient owns the drug – not the facility. This is true even if the drug is solely under the control of a facility's healthcare staff for administration of the drug(s).

Donating Facilities [SEC. 2, H&SC 150202] — Existing law allows skilled nursing facilities (SNF), as defined, manufacturers and wholesalers to donate medications to a SMCD program. This bill would include eleven additional types of facilities that could donate unused medications to a drug repository and distribution program. SNFs are licensed by the Department of Public Health and in all cases the medications are under the control of health care staff. This bill would allow for the donation of drugs from some facilities that *may* allow the patient to maintain possession of the drugs (correctional, residential care, etc.).

Board Authority – This measure allows the Board of Pharmacy, a county board of supervisors, or a county public health officer to prohibit a "participating entity" from participating, if the entity does not comply with the provisions of the program. However, there is no board involvement in the establishment of such a program, nor are there provisions that require board approval to participate in such a program. How will the board go about "prohibiting" these "participating entities"?

Drug Storage & Transfer – Current law requires that donated drugs must be kept physically separate from a pharmacy's or clinic's other drug supply.

This bill allows for the permissive transfer of donated drugs from one approved program to another. According to the author, this would allow donated drugs to be directed where they are needed most. The bill specifies there shall be "complete records of the acquisition and disposition" of donated drugs. It is unclear what 'complete records' shall include. Likewise, SB 1329 is silent on how drugs transfers are to be made.

Pedigree – The bill specifies that a recipient of donated medications shall follow the same pedigree requirements for a donated drug as it would for drugs purchased from a Wholesaler or Manufacturer. Under current law, pedigree stops when the drug is dispensed to a patient. [SEC. 3 (n)]

Physician Oversight – When determining if a donated drug meets the requirements of the division, this bill requires a physician to adhere to "standard pharmacy practices." Pharmacy Law applies to pharmacists and those under the board's jurisdiction. The Board does not have jurisdiction over physicians. [SEC. 3 H&SC 150204 (f)]

Drug Disposal – SB 1329 specifies that donated medications that are not eligible for redistribution shall be destroyed or returned to a *reverse distributor*. The author's fact sheet states this measure would reduce needless *pharmaceutical waste*. Under current law, ⁴pharmaceutical waste is required to be disposed of in accordance with the Medical Waste Management Act (i.e., medical waste hauler). If a donated drug does not meet the standards of the division, should it be disposed of as pharmaceutical waste?

⁴ Medical Waste Management Act, Health and Safety Code Section 117747

Legislation and Regulation Committee

At the Legislation and Regulation Committee meeting held April 24, 2012, Senator Simitian provided a summary of the bill's intent and answered questions from committee members. The committee spoke in support of the intent of the measure, and of their desire to work with the author to address various issues.

Introduced by Senator Simitian

February 16, 2011

An act to amend Sections 47115 and 47116 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 419, as introduced, Simitian. Solid waste: home-generated sharps. Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

This bill would require the above plan to be submitted in an electronic format as prescribed by the department. The bill would require the manufacturer to post and maintain a copy of the plan in a readily accessible location on its Internet Web site.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 47115 of the Public Resources Code is 2 amended to read:
- 3 47115. A pharmaceutical manufacturer that sells or distributes
- 4 a medication in California that is usually intended to be
- 5 self-injected at home through the use of a hypodermic needle, pen
- 6 needle, intravenous needle, or any other similar device, shall, on
- 7 or before July 1, 2010, and annually thereafter, submit to the board,

 $SB 419 \qquad \qquad -2-$

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or its successor agency department, a plan that describes how the manufacturer supports the safe collection and proper disposal of the waste devices. The plan shall be submitted in an electronic format as prescribed by the department.

- SEC. 2. Section 47116 of the Public Resources Code is amended to read:
- 47116. (a) The manufacturer shall post and maintain a copy of the plans required pursuant to Section 47115 *in a readily accessible location* on its Internet Web site.
- (b) The board, or its successor agency, department shall post and maintain copies of the plans submitted by the manufacturers pursuant to Section 47115 on its Internet Web site.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: SB 419 VERSION: Introduced February 16, 2011

AUTHOR: Simitian SPONSOR:

COMMITTEE RECOMMENDATION: None

SUBJECT: Solid Waste: Home-Generated Sharps

Affected Sections: Amend Sections 47115 and 47116 of the Public Resources Code related

to solid waste.

Current Status: On the Assembly Inactive File (1/9/12)

EXISTING LAW:

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources and Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

THIS BILL:

Would require that a pharmaceutical manufacturer to submit the required report in an electronic format, and that the plan be in a readily accessible location on its Internet Web site.

FISCAL/ECONOMIC IMPACT:

No fiscal impact, as introduced.

HISTORY:

- Date Action
- 2012
- Jan. 9 Ordered to inactive file on request of Assembly Member Allen
- 2011
- Sep. 1 From inactive file. Ordered to third reading.
- Aug. 31 Notice of intention to remove from inactive file given by Assembly Member Charles Calderon.
- Aug. 15 From consent calendar. Ordered to third reading. Ordered to inactive file on request of Assembly Member Charles Calderon.
- July 14 Read second time. Ordered to consent calendar.
- July 13 From committee: Do pass. Ordered to consent calendar. (Ayes 16. Noes 0.)
- June 28 From committee. Do pass and re-refer to Com. on APPR (Ayes 9. Noes 0.) Re-referred to Com. on APPR.
- May 2 Referred to Com. on E.S. & T.M.
- Apr. 25 In Assembly. Read first time. Held at Desk.
- Apr. 25 Read third time. Passed. (Ayes 32. Noes 8. Page 708.) Ordered to the Assembly.
- Apr. 12 Read second time. Ordered to third reading.
- Apr. 11 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
- Apr. 1 Set for hearing April 11.
- Mar. 22 From committee: Do pass and re-refer to Com. on APPR (Ayes 5. Noes 0. Page 414.) (March 21). Re-referred to Com. on APPR.
- Mar. 10 Set for hearing March 21.
- Feb. 24 Referred to Com. on E.Q.
- Feb 17 From printer. May be acted upon on or after March 19.
- Feb. 16 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Hernandez (Principal coauthor: Assembly Member Mitchell)

(Coauthor: Senator Emmerson)

February 23, 2012

An act to add Section 4064.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, as amended, Hernandez. Prescription drugs: 90-day supply. Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law prohibits a person from furnishing a dangerous drug except upon the prescription of specified practitioners, except as specified. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a generic drug product or a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements. Existing law also authorizes a pharmacist to refill a prescription for a dangerous drug without the prescriber's authorization under specified circumstances.

This bill would authorize a pharmacist to dispense up to a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription if the pharmacist is exercising his or her professional judgment, he or she dispenses no more than the total amount prescribed, including refills, and the prescriber has not specified on the

SB 1301 -2-

prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4064.5 is added to the Business and 2 Professions Code, to read:
- 4064.5. (a) A pharmacist may dispense up to a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies the initial dispensing of a lesser amount followed by periodic refills of that amount if all of the following requirements are satisfied:

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(1) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(b)

(2) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

16 (e)

- (3) The pharmacist is exercising his or her professional judgment.
- (b) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NO.: SB 1301 VERSION: A – April 16, 2012

Hernandez

AUTHOR: Coauthors: Mitchell Committee Recommendation: Support

and Emmerson

SUBJECT: Prescription Drugs: 90-Day Supply

Affected Sections: Add Section 4064.5 to the Business and Professions Code.

CURRENT STATUS:

April 23, 2012 – Passed out of SEN Committee on Business, Professions and Economic Development.

Referred to Senate Appropriations

EXISTING LAW:

- 1. B&PC § 4024 defines "Dispense" as the furnishing of drugs or devices upon a prescription from an authorized prescriber, and also refers to the furnishing of drugs or devices directly to a patient by a prescriber, as specified.
- 2. B&PC § 4063 specifies "No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed."
- 3. B&PC § 4064 provides for the emergency refilling of a prescription without prescriber authorization.
- 4. 16 CCR Section 1716 precludes a pharmacist from deviating from the requirements of a prescription, except upon consent of the prescriber, or to select another drug product in accordance with B&PC § 4063.

THIS BILL WOULD:

- 1. Add Section 4064.5 to the Business and Professions Code to specify limited circumstances by which a pharmacist may dispense not more than a 90-day supply of a dangerous drug (not a controlled substance) pursuant to a valid prescription for a lesser amount, with refills (such as 30-day supply), so long as specified requirements are met:
 - The patient has completed an initial 30-day supply of the drug, AND all of the following requirements are met:
 - The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.
 - ii. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary; and

- iii. The pharmacist is exercising his or her professional judgment.
- The pharmacist notifies the prescriber of the change in the quantity of dosage units dispensed.
- The provisions would not apply to psychotropic medication or psychotropic drugs, as specified.

AUTHOR'S INTENT:

According to the author, SB 1301 would permit a pharmacist to dispense a refill prescription drug in a 90-day supply, unless the prescriber indicates otherwise on the prescription document. This could save a patient time and money and would aid in a patient's adherence to a prescribed medication therapy.

COMMENTS:

Under current law, a pharmacist may dispense a 90-day supply of a dangerous drug (other than a controlled substance) pursuant to a valid prescription for a lesser amount, so long as the pharmacist receives authorization from the prescriber. This measure would establish limited conditions by which a pharmacist can dispense a 90-day supply after the patient has completed a 30-day supply of that drug, and provided the pharmacist notifies the prescriber of the change in dosage units dispensed.

However, the board's regulation at 16 CCR 1716 specifies that a pharmacist **shall not** deviate from the requirements of a prescription, except as specified. If enacted, the board's regulation may require amendment so as to not conflict with the provisions of the bill.

SB 1301 is silent as to patient interaction. Thus, a pharmacist, complying with the provisions of the bill, would be able to dispense a 90-day supply of a prescription drug without knowing if the patient **wants** a 90-day supply. Board staff believes there should be some level of interaction with the patient to determine if the patient wants an amount greater than what the prescription is written for.

HISTORY:

2012	
Date	Action
Apr. 13	Set for hearing April 23.
Apr. 12	From committee: Do pass as amended and re-refer to Com. On B., P. & E.D.
Mar 29	From committee with author's amendments. Read second time and amended. Re-referred to Com. on
	HEALTH.
Mar. 27	Set for hearing April 11
Mar. 22	Set, first hearing. Hearing canceled at the request of author.
Mar. 13	Set for hearing March 28.
Mar. 8	Referred to Coms. On HEALTH and B., P. & E.D.
Feb. 24	From printer. May be acted upon on or after March 25.
Feb. 23	Introduced. Read first time. To Com. On RLS for assignment. To print.

AMENDED IN SENATE JANUARY 17, 2012 AMENDED IN ASSEMBLY MARCH 30, 2011 AMENDED IN ASSEMBLY MARCH 15, 2011 AMENDED IN ASSEMBLY MARCH 7, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 389

Introduced by Assembly Member Mitchell

(Principal coauthor: Senator Pavley)

February 14, 2011

An act to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

 $AB 389 \qquad \qquad -2 -$

The people of the State of California do enact as follows:

SECTION 1. Article 5 (commencing with Section 125286.10) is added to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.10. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15. The Legislature hereby finds and declares all of the following:

- (a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.
- (b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.
- (c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.
- (d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.
- (e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.
- (f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia

-3-**AB 389**

and other bleeding disorders, reduces mortality and bleeding-related 2 hospitalizations according to the federal Centers for Disease 3 Control and Prevention and the Medical and Scientific Advisory 4 Council of the National Hemophilia Foundation.

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- (g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.
- (h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:
- (1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.
- (2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20. Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

- (a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.
- (b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.
- (c) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.
- (d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor factor VII, factor VIIa, Factor factor VIII, and

AB 389 —4—

Factor factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

- (e) "Emergency" means care as defined in Section 1317.1.
- (f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.
- (g) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.
- (h) "Home nursing services" means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.

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(h) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

25 (j)

(i) "Patient" means a person needing a blood clotting product for home use.

28 (k)

- (*j*) (1) "Provider of blood clotting products for home use" means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:
 - (A) Hospital pharmacies.
 - (B) Health system pharmacies.
- 34 (C) Pharmacies affiliated with hemophilia treatment centers.
- 35 (D) Specialty home care pharmacies.
- 36 (E) Retail pharmacies.
- 37 (2) The providers described in this subdivision may also provide
- 38 home nursing services for persons with bleeding disorders.
- 39 (3)

5 AB 389

(2) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25. Each provider of blood clotting products for home use shall meet all of the following requirements:

- (a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.
- (b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.
- (c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.
- (d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.
- (e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.
- (f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).
- (g) When home nursing services are necessary, as determined by the treating physician, provide these services either directly or through a qualified third party with experience in treating bleeding disorders and coordinate pharmacy services with the third party when one is used to provide home nursing services.

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1 (h)

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(i)

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, medications, and home nursing services and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(j)

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(k)

(*j*) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

28 (l)

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

31 (m)

(1) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(n)

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

39 (o)

7 AB 389

- (*n*) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- 4 125286.30. The California State Board of Pharmacy shall 5 administer and enforce this article.
- 125286.35. Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood
- 10 clotting products for home use.

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Assembly Bill 389

Hemophilia – Standards for Clotting Factor in Home Setting
Assemblymember Holly Mitchell (D – 47)

ISSUE

For people with hemophilia, and other bleeding disorders, it is often necessary that they receive intravenous injection or infusion of prescription blood clotting products several times a week. Most patients use these products at home.

Currently, pharmacies that provide clotting factor to patients on state programs: Medi-Cal, CA Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) must comply with standards that are included in written contracts with the State.

Because these standards are not established for pharmacy providers with patients on private insurance, patients have endured some difficulties in receiving their products. For example, clotting factor has been left on patients' front porches resulting in spoilage due to the heat. Clotting factor is lifesaving for patients and needs to be available on a regular and emergency basis. Additionally, spoilage causes financial hardship as it is an expensive biological product.

BACKGROUND

Currently, there are no standards in State law that governs the proper storage and delivery of blood clotting products for private patients.

THIS BILL

AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, and other bleeding disorders.

SUMMARY

AB 389 creates a uniform standard for both public and private pay patients who receive clotting factors. This bill will assure that both public and private pay patients receive the same standard of care.

SUPPORT

- Hemophilia Council of CA (sponsor)
- Accredo Health Group Inc.
- Baxter Healthcare
- California Academy of Family Physicians
- California Medical Association
- California Pharmacists Association
- California Society of Health System Pharmacists
- Community Healthcare Services
- CSL Behring
- DLA Piper
- DRG Pharmacy LLC
- Federal Hemophilia Treatment Centers
 Region XI
- Grifols, Inc.
- Hemophilia Foundation of Northern California
- Herndon Pharmacy
- Meyer Family Cellars
- National Cornerstone Healthcare Services, Inc.
- Pfizer
- Red Chip Enterprises
- Talecris Biotherapeutics
- UC Davis Medical Center
- Walgreens

OPPOSITION

None

VOTES

Senate AppropriationsSenate Health8-0

•	Assembly Floor	78-0
•	Assembly Appropriations	12-3
•	Assembly Health	15-3
•	Assembly BP &CP	9-0

FOR MORE INFORMATION

Contact: Tiffany Jones
<u>Tiffany.jones@asm.ca.gov</u>
(916) 319-2047





California State Board of Pharmacy 1625 N. Market Blvd, N219, Sacramento, CA 95834 Phone: (916) 574-7900 Fax: (916) 574-8618 www.pharmacy.ca.gov

August 18, 2011

The Honorable Holly Mitchell Member, California State Assembly State Capitol, Room 2176 Sacramento, CA 95816

RE: AB 389

Dear Assembly Member Mitchell:

I regret to advise you that the Board of Pharmacy has taken an oppose position on your AB 389. This bill would codify a number of current standards of practice for pharmacies that dispense blood clotting products to patients with bleeding disorders. I recognize the lateness of notification, and I apologize for the timing.

The board believes that pharmacies that service patients with bleeding disorders are typically specialized in providing such care, have close relationships with their patients and comply with all of the standards in this bill, with the exception of arranging for nursing services (which is usually outside the realm of pharmacy). We are not aware of any problems in the care provided by pharmacies to patients with bleeding disorders and cannot recall a situation were the board has received a complaint in this area.

As such, without a compelling need to establish specially codified provisions for a medical condition, the board is hesitant to endorse such requirements because they seem unnecessary and could lead to a plethora of additional specialized requirements in law for patients with other conditions. The result would be a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care.

I had the pleasure of meeting with Tiffany Jones of your staff and the sponsors of this bill early this summer, and I strongly encouraged them to file complaints with the board when they question the quality of pharmacy care or products provided to them. Without such complaints, the board finds it difficult to fulfill its consumer protection mandate. They agreed to do so in the future, and this will aid us in identifying and resolving issues for these patients should problems arise.

Please do not hesitate to contact me at (916) 574-7911 with questions.

Sinderely,

VIRGINIA HEROL Executive Officer

Assembly Bill 389

Hemophilia – Standards for Clotting Factor in Home Setting
Assemblymember Holly Mitchell (D – 47)

ISSUE

For people with hemophilia, and other bleeding disorders, it is often necessary that they receive intravenous injection or infusion of prescription blood clotting products several times a week. Most patients use these products at home.

Currently, pharmacies that provide clotting factor to patients on state programs: Medi-Cal, CA Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) must comply with standards that are included in written contracts with the State.

Because these standards are not established for pharmacy providers with patients on private insurance, patients have endured some difficulties in receiving their products. For example, clotting factor has been left on patients' front porches resulting in spoilage due to the heat. Clotting factor is lifesaving for patients and needs to be available on a regular and emergency basis. Additionally, spoilage causes financial hardship as it is an expensive biological product.

BACKGROUND

Currently, there are no standards in State law that governs the proper storage and delivery of blood clotting products for private patients.

THIS BILL

AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, and other bleeding disorders.

SUMMARY

AB 389 creates a uniform standard for both public and private pay patients who receive clotting factors. This bill will assure that both public and private pay patients receive the same standard of care.

SUPPORT

- Hemophilia Council of CA (sponsor)
- Accredo Health Group Inc.
- Baxter Healthcare
- California Academy of Family Physicians
- California Medical Association
- California Pharmacists Association
- California Society of Health System Pharmacists
- Community Healthcare Services
- CSL Behring
- DLA Piper
- DRG Pharmacy LLC
- Federal Hemophilia Treatment Centers
 Region XI
- Grifols, Inc.
- Hemophilia Foundation of Northern California
- Herndon Pharmacy
- Meyer Family Cellars
- National Cornerstone Healthcare Services, Inc.
- Pfizer
- Red Chip Enterprises
- Talecris Biotherapeutics
- UC Davis Medical Center
- Walgreens

OPPOSITION

None

VOTES

Senate AppropriationsSenate Health8-0

•	Assembly Floor	78-0
•	Assembly Appropriations	12-3
•	Assembly Health	15-3
•	Assembly BP &CP	9-0

FOR MORE INFORMATION

Contact: Tiffany Jones
<u>Tiffany.jones@asm.ca.gov</u>
(916) 319-2047



CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 389 VERSION: Amended January 17, 2012

AUTHOR: Mitchell SPONSOR: Hemophelia Council of California

BOARD POSITION: Oppose (Reaffirmed January 2012)

SUBJECT: Bleeding Disorders: Blood Clotting Products

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of

Part 5 of Division 106 of the Health and Safety Code

Current Status: In the Senate. On Third Reading File (4/19/12)

EXISTING LAW:

1. Establishes the Holden-Moscone-Garamendi Genetically Handicapped Person's Program within the Department of Health Care Services. [H&SC § 125125]

- 2. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically disabling conditions, including hemophilia. [H&SC § 125130]
- 3. Requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons as specified and sets forth the criteria that the division shall use in considering courses. [B&PC § 2191]

THIS BILL WOULD:

- 1. Add Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act that includes the following:
 - a. Findings and declarations about bleeding disorders, history of and treatment of such disorders, pharmacies role in the delivery of products, identification of persons eligible for treatment through various programs, and states that this article is necessary for the benefit of persons with bleeding disorders to establish standards of service and to promote cost effective, life saving products for home use.
 - b. Defines various terms for purposes of this article including:
 - i. "assay"
 - ii. "ancillary infusion equipment and supplies"
 - iii. "bleeding disorder"
 - iv. "blood clotting product
 - v. "emergency"

- vi. "hemophilia"
- vii. "hemophilia treatment center"
- viii. "home use"
- ix. "patient"
- x. "provider of blood clotting products" to mean specified pharmacies that dispense blood clotting factors for home use, unless excepted
 - 1. Hospital pharmacies
 - 2. Health system pharmacies
 - 3. Pharmacies affiliated with hemophilia treatment centers
 - 4. Specialty home care pharmacies
 - 5. Retail pharmacies
- xi. And that the above providers shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.
- c. Requires that each provider, as defined above, meet the following requirements:
 - i. Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescriber and ensure quality care.
 - ii. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of product on hand as well and understanding about proper storage and refrigeration.
 - iii. Maintain 24-hour on-call service seven days a week, 365 days a year.
 - iv. Have the ability to obtain all brands of the products approved by the FDA in multiple assay ranges as specified.
 - v. Supply all necessary ancillary infusion equipment and supplies as needed.
 - vi. Store, ship, or otherwise deliver, all products in conformity with state and federally mandated standards.
 - vii. Ship product within two business days to a patient for a nonemergency prescription.
 - viii. For emergencies, deliver products, ancillary equipment, supplies and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, or within one day for patients living outside that area.
 - ix. Provide contact information to a patient to report problems with delivery.
 - x. Provide patient with product recall and withdrawal notifications within 24 hours.
 - xi. Provide language interpretive service via phone or in person, as needed.
 - xii. Have a detailed plan in the event of a natural or manmade disaster.
 - xiii. Provide appropriate record keeping.
 - xiv. Comply with HIPAA requirements.
- 2. Requires the California Board of Pharmacy to administer and enforce this article.

AUTHOR'S INTENT:

According to the author's office, "AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, von Willebrand disease and other bleeding disorders."

COMMENTS:

Many of these provisions in AB 389 are currently the standard of practice, but are not codified. This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received. The board would already have jurisdiction to investigate consumer complaints involving poor service or product delivery that resulted in either patient harm or the potential for harm. We are unaware of any such complaints received by the board.

There are potential challenges in enforcing some of these provisions. Specifically, the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting factor on hand as required.

A previous version of this bill contained a provision requiring the Licensing Division of the Medical Board to consider requiring a continuing education course on bleeding disorders. This provision was amended out of the measure on March 30, 2011. Previous provisions related to the requirement that a provider provide home nursing services were amended out the measure on January 17, 2012.

PRIOR BOARD DISCUSSION and ACTION:

The board opposed the measure in August 2011. The board reaffirmed this position at the January 2012 Board Meeting.

In its letter of opposition (8/18/11), the board cited the lack of a compelling need to establish codified provisions for a medical condition which could result in a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care. The board also stated that it was not aware of any problems in the care provided by pharmacies to patients with bleeding disorders based on the lack of complaints in this area.

FISCAL/ECONOMIC IMPACT:

We anticipate a portion of an inspector PY will be necessary to ensure compliance with these provisions. This workload could possibly be absorbed if the board is able to fill all authorized inspector positions. However, because of the bill's specificity and the need for close monitoring of these provisions, the board would need to do frequent inspections. Because the specialty pharmacies are not required to have a separate license, nor are they required to notify the board that they provide such services, performing inspection on all pharmacies that provide these services would be a challenge.

PREVIOUS/RELATED LEGISLATION

SB 1594 (Steinberg, 2007) would have established standards for providers of blood clotting products. The board had a "Watch" position on the bill. The measure later died after being placed on the Senate Appropriations Suspense File and never passed out of the house of origin.

SB 971 (Pavely, 2010) introduced legislation similar to this proposal. The board did not have a position on this bill. This bill was vetoed by the governor.

"I am returning Senate Bill 971 without my signature. This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address. For these reasons, I am unable to sign this bill."

SUPPORT/OPPOSITION:

Support

Hemophilia Council of California (Sponsor)

Accredo Health Group Inc.

Baxter Healthcare

California Academy of Family Physicians

California Medical Association

California Pharmacists Association

California Society of Health System Pharmacists

Community Healthcare Services

CSL Behring

DLA Piper

DRG Pharmacy LLC

Federal Hemophilia Treatment Centers, Region XI Grifols Inc.

Hemophilia Foundation of Northern California

Herndon Pharmacy

Meyer Family Cellars

National Cornerstone Healthcare Services Inc.

Pfizer Inc.

Red Chip Enterprises
Talecris Biotherapeutics

UC Davis Medical Center

Walgreens

Oppose

Board of Pharmacy

HISTORY:

Date Action

2012

- Jan. 18 Read second time. Ordered to third reading.
- Jan. 17 From inactive file. Ordered to second reading. Read second time and amended. Ordered to second reading.

2011

- Sept. 1 From Special Consent Calendar pursuant to Joint Rule 22.2. Ordered to third reading. Ordered to inactive file at the request of Senator Pavley.
- Aug. 31 Ordered to special consent calendar.
- Aug. 23 Read second time. Ordered to third reading.
- Aug. 22 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
- Aug. 15 In committee: Hearing postponed by committee.
- July 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (July 6). Re-referred to Com. on APPR.
- June 23 From committee: Do pass and re-refer to Com. on B., P. & E.D. with recommendation: to consent calendar. (Ayes 8. Noes 0.) (June 22). Re-referred to Com. on B., P. & E.D.
- June 8 In committee: Hearing postponed by committee.
- May 12 Referred to Coms. on HEALTH and B., P. & E.D.
- Apr. 28 In Senate. Read first time. To Com. on RLS. for assignment.
- Apr. 28 Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 1127.)
- Apr. 14 Read second time. Ordered to third reading.
- Apr. 13 From committee: Do pass. (Ayes 12. Noes 3.) (April 13).
- Apr. 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 15. Noes 3.) (April 5). Re-referred to Com. on APPR.
- Mar. 31 Re-referred to Com. on HEALTH.
- Mar. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 22 From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 9. Noes 0.) (March 22). Re-referred to Com. on HEALTH.
- Mar. 16 Re-referred to Com. on B., P. & C.P.
- Mar. 15 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
- Mar. 8 Re-referred to Com. on B., P. & C.P.
- Mar. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
- Feb. 24 Referred to Com. on B., P. & C.P.
- Feb. 15 From printer. May be heard in committee March 17.
- Feb. 14 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 27, 2012 AMENDED IN ASSEMBLY FEBRUARY 6, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1442

Introduced by Assembly Member Wieckowski (Coauthors: Assembly Member Members Allen and Williams)

January 4, 2012

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, and 118032 to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would authorize a medical waste generator or parent organization that employs health care professionals who generate pharmaceuticals to apply to the enforcement agency for a pharmaceutical waste hauling exemption if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements and if the facility receiving the medical

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waste retains specified documentation. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 117637 is added to the Health and Safety 2 Code, to read:
 - 117637. "Common carrier" means either of the following:
 - (a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.
- 8 (b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.
- SEC. 2. Section 117748 is added to the Health and Safety Code, to read:
 - 117748. (a) "Pharmaceutical waste" means any pharmaceutical, as defined in Section 117747, that for any reason may no longer be sold or dispensed for use as a drug.
 - (b) For purposes of this part, "pharmaceutical waste" does not include any pharmaceutical that still has potential value to the generator because it is being returned to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed both as a wholesaler of dangerous drugs by the

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1 California State Board of Pharmacy pursuant to Section 4160 of 2 the Business and Professions Code and as a permitted transfer 3 station pursuant to Section 117775, for possible manufacturer 4 credit.

- SEC. 3. Section 117935 of the Health and Safety Code is amended to read:
- 117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:
- (a) The name of the person.

- 13 (b) The business address of the person.
 - (c) The type of business.
 - (d) The types, and the estimated average monthly quantity, of medical waste generated.
 - (e) The type of treatment used onsite.
 - (f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste,, the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.
 - (g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.
 - (h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.
 - (i) A statement certifying that the information provided is complete and accurate.
- 39 SEC. 4. Section 117945 of the Health and Safety Code is 40 amended to read:

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117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

- (a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.
- (b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, and, if applicable, the name of the common carrier transporting pharmaceutical waste pursuant to Section 118032. The small quantity generator shall maintain these records for not less than two years.
- SEC. 5. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

- (a) The name of the person.
- (b) The business address of the person.
- 24 (c) The type of business.
 - (d) The types, and the estimated average monthly quantity, of medical waste generated.
 - (e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.
 - (f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.
 - (g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.

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(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

- (i) An emergency action plan complying with regulations adopted by the department.
- (j) A statement certifying that the information provided is complete and accurate.
- SEC. 6. Section 118000 of the Health and Safety Code is amended to read:
- 118000. (a) Except as otherwise exempted pursuant to Section 118030 or 118032, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.
- (b) Except for small quantity generators transporting medical waste pursuant to Section 118030 or small quantity generators or common carriers transporting pharmaceutical waste pursuant to Section 118032, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.
- (c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.
- (d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

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(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

- (f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.
- SEC. 7. Section 118032 is added to the Health and Safety Code, to read:
- 118032. A medical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste may apply to the enforcement agency for a pharmaceutical waste hauling exemption if the generator, health care professional, or parent organization meets all of the following requirements:
- (a) The generator or parent organization has on file one of the following:
- (1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117915), a medical waste management plan prepared pursuant to Section 117935.
- (2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117915), the information document maintained pursuant to subdivision (a) of Section 117945.
- (3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.
- (b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

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(c) Except as provided in subdivision (d), the generator maintains and the facility receiving the medical waste maintain a tracking document, as specified in Section 118040.

- (d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:
- (A) The name of the person transporting the pharmaceutical waste.
- (B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate medical waste container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.
 - (C) The date that the pharmaceutical waste was returned.
- (2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the waste.

 $\left(2\right)$

- (3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility—for the purpose of consolidation before treatment and disposal over a period of time, if the form or log is maintained in the files of the parent organization or another health care facility that receives the waste once the form or log is completed, provided the form or log meets the requirements specified in paragraphs (1) and (2).
- SEC. 8. Section 118040 of the Health and Safety Code is amended to read:
- 118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment

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facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

- (b) The tracking document shall include, but not be limited to, all of the following information:
- (1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.
- (2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.
 - (3) The name, address, and telephone number of the generator.
- (4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.
- (5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.
- (c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.
- (d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

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(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

- (f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.
- SEC. 9. Section 118165 of the Health and Safety Code is amended to read:
- 118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:
 - (a) The type of treatment facility and its capacity.
 - (b) All treatment facility operating records.
- (c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators, hazardous waste haulers, or, pursuant to Section 118032, common carriers.
- SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

AB 1442 (Wieckowski)

Co-Authors: Assemblymembers Allen and Williams Common Carriers

PROBLEM

Under existing law, pharmaceutical drugs can be sent to healthcare facilities (HCFs) through standard common carriers, or standard shipping means. Unused drugs can sometimes be returned to the manufacturer for credit, via a common carrier. Expired and non-dispensable drugs must be shipped as "Medical Waste", requiring expensive hazardous waste shipping, instead of common carrier. This is unnecessarily expensive for pharmacies, hospitals, and other health care facilities, who are simply returning the exact same drug that was shipped to them by common carrier.

THIS BILL

The proposed changes to the California Medical Waste Management Act (MWMA) (Health and Safety Code Sections 117600-118360) would allow HCFs to ship all non-dispensable (unwanted) pharmaceuticals designated as "Medical Waste" under the MWMA to permitted Medical Waste Transfer Stations or Treatment Facilities via common carriers for proper processing in accordance with all applicable federal, state and local laws. Presently a substantial portion of unwanted pharmaceuticals at HCF's that are not designated as hazardous under federal law must be handled as Medical Waste under state law. substantially increases processing the and transportation costs associated with disposing of the unwanted pharmaceuticals and encourages HCF's to illegally dispose of the pharmaceuticals via the trash or sewer system.

SUMMARY

In short, under the MWMA, HCF's must process the same unwanted pharmaceutical in different ways and at substantially different costs depending on whether the pharmaceutical drug may be returned to the manufacturer for credit. In light of the risk to the California water supply and environment, allowing HCF's to utilize common carriers for the transportation of all unwanted pharmaceuticals simply makes sense.

FACTS

- Reverse distribution helps business and healthcare facilities save money by returning drugs to pharmaceutical companies for recycling/disposal.
- Reverse distribution helps the environment and water supply by encouraging proper disposal instead of drugs ending up in trash or the sewer system.

STATUS

Introduced January 4th, 2012

Assembly Committee on Environmental Safety & Toxic Materials- March 20, 2012

SUPPORT

EXP Pharmaceutical Services Corp. Fremont Chamber of Commerce

OPPOSITION

None on File

FOR MORE INFORMATION

Contact: Ashley Medina Phone: (916) 319-2020

Email: Ashley.Medina@asm.ca.gov

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 1442 VERSION: Amended March 27, 2012

AUTHOR: Weickowski SPONSOR:

COMMITTEE RECOMMENDATION: Oppose Unless Amended

SUBJECT: Common Carriers to Transport Pharmaceutical Waste

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of

Part 5 of Division 106 of the Health and Safety Code

Current Status: Referred to ASM Appropriations (3/28). As of 4/18/12, no hearing date

has been set.

EXISTING LAW:

1. Establishes the Medical Waste Management Act (MWMA), administered by the State Department of Public Health (DPH) (Health and Safety Code § 117600 et seq.) to include

- a. Requirements for Medical Waste / Small Quantity Generators (Health and Safety Code § 117915-117945), to include
 - Minimum information required to be contained in a small quantity generator's medical waste management plan (H&SC § 117935)
 - ii. Records that must be maintained by a small quantity generator that is not required to register (H&SC § 117945)
- b. Requirements for Medical Waste / Large Quantity Generators (Health and Safety Code § 117950-117995)
- c. The Licensing and Oversight of Medical Waste Haulers, requirements and exemptions (Health and Safety Code § 118000 et seq.)
- d. Recordkeeping Requirements for the Medical Waste Treatment Facilities (Health and Safety Code § 118165)
- 2. Provides for the licensure and regulation of "reverse distributors" by the California State Board of Pharmacy (defined at Business and Professions Code § 4040.5)
- 3. Provides for the management of hazardous waste by the Department of Toxic Substances Control (Health and Safety Code Section 25100 et seq.) and related regulations (11 CCR starting at Section 6626.1)

THIS BILL WOULD:

- 1. Amend the Medical Waste Management Act to allow for the legal handling and transportation of pharmaceutical waste by a common carrier.
 - Specifically, AB 1442 would
 - a. Add a definition of "common carrier." [SEC.1. Section 117637]
 - b. Add a definition of "pharmaceutical waste" as any pharmaceutical (defined at H&SC 117747) that for any reason may no longer be sold or dispensed for use as a drug, excluding those pharmaceuticals that are being returned to a reverse distributor (licensed by the Board) and that also is licensed as permitted transfer station (under H&SC § 117775). [SEC.2. Section 117748]
 - c. Change provisions related to Small Quantity Generators, to include
 - For a small quantity generator that is required to register pursuant to the MWMA, that its medical waste management plan registered with the enforcement agency also include the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal. [SEC.3. Section 17935(f)]
 - ii. For a small quantity generator that is not required to register pursuant to the MWMA, that files maintained in their office also include the name of the common carrier transporting the pharmaceutical waste. [SEC.4. Section 117945(b)]
 - d. Change provisions related to Large Quantity Generators, to include
 - Require that a large quantity generator's medical waste management plan, also include the name and business address of the common carrier transporting pharmaceutical waste. [SEC.5, Section 117960 (f)]
 - e. Exempt from requirements that specify the manner in which medical waste shall be transported to a medical waste treatment facility or permitted transfer station, those with a pharmaceutical waste hauling exemption, a small quantity generator transporting pharmaceutical waste, or a common carrier transporting pharmaceutical waste, as specified. [SEC.6. Section 118000(a) and (b)]
 - f. Specify requirements under which a medical waste generator or parent organization that generates pharmaceutical waste may apply for a "pharmaceutical waste hauling exemption" to include specified recordkeeping requirements [SEC.7. Section 118032]
 - g. Specify that tracking documents of a hazardous waste transporter or generator of medical waste also specify the quantity or aggregate weight of medical waste transported. [SEC.8, Section 118040 §(b)(2)]
 - Require that the records kept and maintained by Medical Waste Treatment Facilities also include tracking documents for generators of pharmaceutical waste.
 [Sec.9. Section 118165(c)]

Technical issues:

Proposed Section 118032 references various documents, or medical waste management plans. With the establishment of the term "pharmaceutical waste," technical amendments may be need to so that the section specifies documents or plans that include provisions specific to 'pharmaceutical waste' (as proposed at H&S 117748).

AUTHOR'S INTENT:

According to the author, AB 1442 would allow healthcare facilities to ship all non-dispensable (unwanted) pharmaceuticals designated as "medical waste" via common carriers. The author states that a substantial portion of unwanted pharmaceuticals at healthcare facilities (not designated as 'hazardous' under federal law) must be handled as medical waste under state law, and the transportation costs associated with the disposal of that waste "encourages healthcare facilities to illegally dispose of the pharmaceuticals via the trash or sewer system." The author further states that allowing healthcare facilities to utilize common carriers for the transportation of "all unwanted pharmaceuticals" simply makes sense.

COMMENTS:

The Medical Waste Management Act (MWMA) currently requires pharmaceutical waste to be managed as "medical waste" which includes such material as infectious and biohazardous waste and other types of waste that have posed a potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. While this is appropriate for large scale medical waste, the management of pharmaceutical waste needs a protective, yet different approach.

This proposal would make amendments to the MWMA to define pharmaceutical waste and to allow for such waste to be transported by a common carrier, yet staff is concerned that the manifesting requirements and tracking of the pharmaceutical waste may not be sufficient to ensure the drugs will not be diverted, scavenged to be sold illegally, or otherwise re-enter the drug supply chain.

The board is not aware of circumstances where healthcare facilities are illegally disposing of pharmaceuticals via the trash or sewer system. While a reasonable approach may be needed for the adequate handling and transportation of pharmaceutical waste, it is imperative that the health and safety of Californian's not be placed at risk through access to discarded drugs.

PRIOR BOARD DISCUSSION and ACTION:

In the previous session, Senator Simitian authored SB 26, which sought to implement provisions for common carriers to pick up and transport pharmaceutical waste (drugs returned to the pharmacy by patients).

In dealing with drug take-back issues, the board has in the past sought amendments to Pharmacy Law that would have allowed pharmaceutical waste to be transported by a licensed integrated waste hauler, given sufficient recordkeeping. The board's proposal specified that a reverse distributor shall not accept the return of dangerous drugs that have been dispensed to patients, which are later returned by the patient to the pharmacy, and would also specify that — if these drugs were accepted by the pharmacy — the drugs shall only be handled by a licensed integrated waste hauler. The board's proposal specified recordkeeping requirements for drugs that were returned to a wholesaler or provided to a reverse distributor, to include:

- the quantity or weight of drugs returned
- the date the drugs were returned
- the names of the reverse distributors or wholesalers to whom the drugs were provided.

Also, records of drugs returned to a licensed integrated waste hauler shall specify

- the volume in weight or measurement of the pharmaceutical waste
- the date
- the name of the licensed integrated waste hauler

As AB 1442, as amended, would apply to a "parent organization that employs health care professionals" it could be interpreted that the provisions could apply to pharmacies who chose to collect unwanted drugs from patients.

COMMITTEE RECOMMENDATION

The Legislation and Regulation Committee discussed the measure and determined that controls need to be included to account for the drugs and to prevent diversion.

SUPPORT/OPPOSITION:

Support

EXP Pharmaceutical Services Corp.

Fremont Chamber of Commerce

HISTORY:

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Date Action
2012

Mar. 22 Referred to Com. on RLS.
Feb. 27 Read first time.
Feb. 25 From printer. May be acted upon on or after March 26.
Feb. 24 Introduced. To Com. on RLS. for assignment. To print.
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Introduced by Assembly Member Valadao

February 24, 2012

An act to amend Section 5024.2 of the Penal Code, relating to prisoners.

LEGISLATIVE COUNSEL'S DIGEST

AB 2369, as introduced, Valadao. Prisoners: pharmacy services.

Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient, that may incorporate a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

This bill would instead require the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 5024.2 of the Penal Code is amended to read:
- 3 5024.2. (a) The Department of Corrections and Rehabilitation
- 4 is authorized to maintain and operate a comprehensive pharmacy
- 5 services program for those facilities under the jurisdiction of the

AB 2369 — 2 —

1 department that is both cost effective and efficient, and may 2 incorporate the following:

- (1) A statewide pharmacy administration system with direct authority and responsibility for program administration and oversight.
- (2) Medically necessary pharmacy services using professionally and legally qualified pharmacists, consistent with the size and the scope of medical services provided.
- (3) Written procedures and operational practices pertaining to the delivery of pharmaceutical services.
- (4) A multidisciplinary, statewide Pharmacy and Therapeutics Committee responsible for all of the following:
 - (A) Developing and managing a department formulary.
- (B) Standardizing the strengths and dosage forms for medications used in department facilities.
- (C) Maintaining and monitoring a system for the review and evaluation of corrective actions related to errors in prescribing, dispensing, and administering medications.
- (D) Conducting regular therapeutic category reviews for medications listed in the department formulary.
- (E) Evaluating medication therapies and providing input to the development of disease management guidelines used in the department.
- (5) A requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

(6)

- (5) Use of an enterprise-based pharmacy operating system that provides management with information on prescription workloads, medication utilization, prescribing data, and other key pharmacy information.
- (b) The comprehensive pharmacy services program shall require the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

(b)

(c) The department is authorized to operate and maintain a centralized pharmacy distribution center to provide advantages of scale and efficiencies related to medication purchasing, inventory control, volume production, drug distribution, workforce utilization,

-3- AB 2369

and increased patient safety. It is the intent of the Legislature that the centralized pharmacy distribution center and institutional pharmacies be licensed as pharmacies by the California State Board of Pharmacy meeting all applicable regulations applying to a pharmacy.

- (1) To the extent it is cost effective and efficient, the centralized pharmacy distribution center should include systems to do the following:
- (A) Order and package bulk pharmaceuticals and prescription and stock orders for all department correctional facilities.
- (B) Label medications as required to meet state and federal prescription requirements.
- (C) Provide barcode validation matching the drug to the specific prescription or floor stock order.
- (D) Sort completed orders for shipping and delivery to department facilities.
- (2) Notwithstanding any other requirements, the department centralized pharmacy distribution center is authorized to do the following:
- (A) Package bulk pharmaceuticals into both floor stock and patient-specific packs.
 - (B) Reclaim, for reissue, unused and unexpired medications.
- (C) Distribute the packaged products to department facilities for use within the state corrections system.
- (3) The centralized pharmacy distribution center should maintain a system of quality control checks on each process used to package, label, and distribute medications. The quality control system may include a regular process of random checks by a licensed pharmacist.

(e)

(d) The department may investigate and initiate potential systematic improvements in order to provide for the safe and efficient distribution and control of, and accountability for, drugs within the department's statewide pharmacy administration system, taking into account factors unique to the correctional environment.

36 (d)

(e) The department should ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable law, rules,

AB 2369 —4—

regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients.

- (f) On March 1, 2012, and each March 1 thereafter, the department shall report all of the following to the Joint Legislative Budget Committee, the Senate Committee on Appropriations, the Senate Committee on Budget and Fiscal Review, the Senate Committee on Health, the Senate Committee on Public Safety, the Assembly Committee on Appropriations, the Assembly Committee on Budget, the Assembly Committee on Health, and the Assembly Committee on Public Safety:
- (1) The extent to which the Pharmacy and Therapeutics Committee has been established and achieved the objectives set forth in this section, as well as the most significant reasons for achieving or not achieving those objectives.
- (2) The extent to which the department is achieving the objective of operating a fully functioning and centralized pharmacy distribution center, as set forth in this section, that distributes pharmaceuticals to every adult prison under the jurisdiction of the department, as well as the most significant reasons for achieving or not achieving that objective.
- (3) The extent to which the centralized pharmacy distribution center is achieving cost savings through improved efficiency and distribution of unit dose medications.
- (4) A description of planned or implemented initiatives to accomplish the next 12 months' objectives for achieving the goals set forth in this section, including a fully functioning and centralized pharmacy distribution center that distributes pharmaceuticals to every adult facility under the jurisdiction of the department.
- (5) The costs for prescription pharmaceuticals for the previous fiscal year, both statewide and at each adult prison under the jurisdiction of the department, and a comparison of these costs with those of the prior fiscal year.

35 (1

(g) The requirement for submitting a report imposed under subdivision—(e) (f) is inoperative on March 1, 2016, pursuant to Section 10231.5 of the Government Code.

AB 2369 (Valadao)

Department of Corrections & Rehabilitation: Pharmacy Services

SUMMARY

AB 2369 would require the Department of Corrections and Rehabilitation (CDCR) to use generic medications in their pharmacy services program for inmates. There will still be an exception approval process for brand name medications under the acting physician's care, or if a generic version of the prescribed medication is unavailable.

PROBLEM

As management of prison health care services transitions out of the control of the federal Receiver and back to the jurisdiction of CDCR, it is critical that fiscal responsibility is maintained while upholding quality patient care.

Generic medications are an excellent way to maintain fiscal responsibility as they have the equivalent active ingredient as the brand name versions and must work under the same safety and effectiveness standards as approved by the FDA, yet the cost is significantly less. However, there is no current requirement to use generic medications within the penal code.

EXISTING LAW

Under Penal Code section 5024.2, CDCR is currently *authorized* to maintain and operate a comprehensive pharmacy services program that <u>may</u> incorporate a requirement for use of generic medications.

THE SOLUTION

Strengthening the current code to make generic drugs mandatory when prescribing drugs to inmates (except in special physician-approved circumstances), is a common sense policy that should be adopted in order to keep health care costs lower.

FISCAL EFFECT

Unknown at this time.

SPONSOR

Author

For more information:

Contact: Christina Chiappe at (916) 319-2030

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 2369 VERSION: Introduced February 24, 2012

AUTHOR: Valadao SPONSOR: Author

COMMITTEE RECOMMENDATION:

SUBJECT: Prisoners: Pharmacy Services

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: 4/25/12 – Do pass from Assembly Committee on Business, Professions

and Consumer Protection. Re-referred to Assembly Appropriations.

EXISTING LAW:

1. Requires the Department of Corrections and Rehabilitation's (CDCR) to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient.

- 2. Permits the CDCR to incorporate a number of components into its comprehensive pharmacy services program, to include a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.
- 3. Pharmacy Law, Section 4073 of the Business and Professions Code, authorizes a pharmacist filling a prescription order to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as specified, of those drugs having the same active chemical ingredient.

THIS BILL:

1. Would amend the provisions of Section 5024.2 to require that the comprehensive pharmacy services program include a *requirement* for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

AUTHOR'S INTENT:

The author states "as management of prison health care services transitions out of the control of the federal Receiver and back to the jurisdiction of CDCR, it is critical that fiscal responsibility

is maintained while upholding quality patient care." The author further states that generic medications are an excellent way to maintain fiscal responsibility as they have the equivalent active ingredient as the brand name versions and must work under the same safety and effectiveness standards as approved by the FDA, yet the cost is significantly less.

COMMENTS:

As introduced, no impact to Pharmacy Law. The Legislation and Regulation Committee did not make a recommendation on this measure.

SUPPORT/OPPOSITION:

According to the ASM Com. on Business Professions and Consumer Protection (4/17):

Support

Peace Officers Research Association of California

Oppose

BayBio

Mental Health America of California

HISTORY:

Date Action
2012
Mar. 22 Referred to Coms. on B., P. & C.P. and HEALTH.
Feb. 27 Read first time.
Feb. 26 From printer. May be heard in committee March 27.
Feb. 24 Introduced. To print.

AMENDED IN ASSEMBLY MARCH 29, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 2348

Introduced by Assembly Member Mitchell (Principal coauthor: Assembly Member Chesbro)

February 24, 2012

An act to amend Section 2725.1 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2348, as amended, Mitchell. Registered nurses: dispensation of drugs.

Existing law, the Nursing Practice Act, authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic.

This bill would make a nonsubstantive change to these provisions., in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 2725.1 of the Business and Professions
- 2 Code is amended to read:

AB 2348 -2-

2725.1. (a) Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon or an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a licensed primary care clinic as defined in paragraphs (1) and (2)of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of, the Health and Safety Code.

- (b) Notwithstanding any other provision of law, a registered nurse may dispense hormonal contraceptives pursuant to standardized procedures developed in compliance with subdivision (c) of Section 2725 if the nurse is functioning within a licensed primary care clinic as defined in subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b), (c), or (h) of Section 1206 of, the Health and Safety Code.
- (c) No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

Assembly Bill 2348

Access to Birth Control Assemblymember Holly Mitchell (D – 47)

ISSUE

Across California, many women lack access to birth control, leaving them at significant risk of unintended pregnancy. In some parts of the state, patients of community health clinics cannot access hormonal contraceptives because of the limited supply of prescribers and others who are legally authorized to order or furnish these medications. Lack of enough appropriate staff can result in health centers closing or reducing hours, compounding many communities' unmet family planning needs. For a woman in need of birth control these types of shortages can mean waiting long periods of time to schedule a health center appointment, sitting in a waiting room for hours before being seen, or driving long distances to see a provider. All of these barriers place her at greater risk of unintended pregnancy.

BACKGROUND

While the Family PACT program serves 1.82 million women annually, overall only 71% of the women in need of family planning received services through Family PACT or Medi-Cal. Unmet need for family planning varies widely by county, of the 10 counties with the highest need, the proportion who accessed services ranged from 46% in San Bernardino to 75% in San Diego, with the greatest need in rural areas.

Need for the program has increased 12% since FY 2005-06, yet the percentage of patients in need who accessed services has dropped by 6% (FPACT Program Report, 2009-10). This gap is likely to become increasingly acute with the addition of the estimated 5-6 million California residents to be insured under national health reform.

Women with unintended pregnancies are more likely to receive later or no prenatal care, to smoke and consume alcohol during pregnancy (Contraception, 2009), to be depressed during pregnancy, to experience domestic violence during pregnancy, and have a higher rate of maternal death. The health consequences for the newborn are dire, including preterm birth and low birth weight, both associated with infant mortality.

essential component of comprehensive reproductive health care for women, hormonal contraceptives are among the safest medications available today. Many respected medical institutions, including the World Health Organization (WHO), the American College of Obstetricians and Gynecologists (ACOG) and Planned Parenthood Federation of America (PPFA), have developed evidence-based guidelines for hormonal contraceptive use based on a self-reported medical history and measurement of blood pressure. All of these guidelines acknowledge that hormonal contraception can be safely provided and utilized without requiring a pelvic examination.

The Institute of Medicine (IOM) Committee on Women's Health Research recently reported a universal need for making contraceptives more available, accessible, and acceptable (IOM, 2010b). There are several barriers that women often face that keep them from being able to successfully and correctly utilize their birth control method, among these are expensive co-pays, insurance coverage limitations on prescriptions, and the difficulty or delay when scheduling an office visit.

EXISTING LAW

Current law allows for the prescribing or furnishing of drugs, including birth control, by physicians and surgeons, nurse practitioners, certified nurse midwives, and physician's assistants. RNs in community clinics have the authority to dispense drugs based on an order from a physician or surgeon, they currently serve in this capacity by dispensing birth control to community clinic patients.

THIS BILL

This bill would build on current law by allowing RNs to dispense hormonal contraceptives, including birth control pills, transdermal contraceptive patch, and vaginal contraceptive ring, pursuant to a standardized procedure.

The Nurse Practice Act (B&P Code §2725) specifies that a standardized procedure must be developed collaboratively by the nurses, physician, and administration of a health center. Because of this interdisciplinary collaboration, there is accountability on several levels for the activities to be performed by the registered nurse.

Utilizing a standardized procedure would allow RNs to provide hormonal contraceptives to patients after the RN conducts a patient assessment based on approved medical guidelines. This includes reviewing basic health indicators like age and blood pressure and analyzing the patient's health history including history of smoking and relevant cancers in order to dispense the appropriate birth control for the patient.

SUMMARY

This bill will expand access to birth control, an essential component of women's preventive health care, by allowing RNs to dispense hormonal birth control under a standardized procedure. Increasing access while maintaining the safety of current medical guidelines will help address the significant unmet need faced by across the state.

SUPPORT

- Planned Parenthood Affiliates of California (Sponsor)
- California Family Health Council (Sponsor)

American Nurses Association of CA

OPPOSITION

None at this time

FOR MORE INFORMATION

Contact:

 Elise Flynn Gyore, 916-319-2047 elise.gyore@asm.ca.gov

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 2348 VERSION: Introduced February 24, 2012

AUTHOR: Mitchell SPONSORS: Planned Parenthood Affiliates of Ca.

California Family Health Council

RECOMMENDED BOARD POSITION: None

SUBJECT: Registered nurses: dispensation of drugs

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: 4/17/12 – First hearing in ASM Committee on Business, Professions and

Consumer Protection. Failed passage. Reconsideration granted.

EXISTING LAW:

1. Provides for the scope of practice of a Registered Nurse under the authority of the Nursing Practice Act, administered by the Board of Registered Nursing (Business and Professions Code Section 2700 et seq.).

- 2. A registered nurse is authorized to dispense drugs or devices in a clinic licensed pursuant to Sections 1204 or 1206, as specified. With limited exceptions, a nurse shall not dispense controlled substances. (Business and Professions Code Section 2725.1)
- 3. The following clinics are specified in the Health and Safety Code:
 - § 1204(a) Primary Care Clinics, which include "community clinics" and "free clinics" (Licensed by Department of Public Health)
 - The following clinics are exempt from licensure by the Department of Public Health:
 - b. § 1206(b) A government operated clinic, as specified.
 - c. § 1206(c) A clinic operated by a federally recognized Indian tribe or tribal organization, as specified.
 - d. § 1206(h) A clinic that is operated by a primary care community or free clinic that is operated as an "intermittent clinic' (one with limited hours of service, as specified.

THIS BILL WOULD:

- 1. Specify that in a clinic licensed pursuant to Section 1204(a) or Section 1206(b) or (c) a nurse may dispense drugs or devices upon an order by a licensed physician and surgeon or on order issued by a certified nurse-midwife, nurse practitioner, or physician assistant, as specified.
- 2. Specify that a registered nurse may dispense hormonal contraceptives in a primary care clinic (defined at Section 1204(a) of the Health and Safety Code) or in a clinic (defined at Section 1206 (b) (c) or (h) of the Health and Safety Code pursuant to an established protocol.

AUTHOR'S INTENT:

According to the author, utilizing a standardized procedure (protocol) would allow a Registered Nurse with the ability to provide hormonal contraceptives to patients after the RN conducts a patient assessment pursuant to approved medical guidelines. This includes reviewing basic health indicators like age and blood pressure, and analyzing the patient's health history. Further, the author states that AB 2348 will expand access to birth control by allowing RNs to dispense these drugs under a protocol, thereby helping to meet the needs of women.

COMMENTS:

Information obtained from the Board of Registered indicates that a registered nurse would be able to perform these duties if deemed clinically competent to do so by the supervising physician, nurse practitioner, certified nurse-midwife or physician assistant.

SUPPORT/OPPOSITION:

Support

California Family Health Council (sponsor)

Planned Parenthood Affiliates of California (sponsor)

Planned Parenthood Mar Monte (sponsor)

Planned Parenthood of Santa Barbara, Ventura and San Luis Obispo Counties, Inc. (sponsor)

Planned Parenthood Pasadena and San Gabriel Valley (sponsor)

Planned Parenthood Shasta Pacific Action Fund (sponsor)

Six Rivers Planned Parenthood (sponsor)

ACCESS Women's Health Justice

California Latinas for Reproductive Justice

Forward Together

Ibis Reproductive Health

Law Students for Reproductive Justice

Maternal and Child Health Access

National Center for Youth Law

National Council of Jewish Women

Nevada County Citizens for Choice

Physicians for Reproductive Choice and Health

United Nurses Associations of California/Union of Health Care Professionals Women's Community Clinic

Oppose

California Association for Nurse Practitioners California Nurses Association

HISTORY:

mstokt.	
Apr. 25	From committee: Do pass and re-refer to Com. on RLS. (Ayes 5. Noes
	3.) (April 24). Re-referred to Com. on RLS.
Apr. 9	Re-referred to Com. on B., P. & C.P.
Mar. 29	Referred to Com. on B., P. & C.P. From committee chair, with
	author's amendments: Amend, and re-refer to Com. on B., P. & C.P.
	Read second time and amended.
Feb. 27	Read first time.
Feb. 26	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

Introduced by Senator Rubio

February 16, 2012

An act to amend Sections 4190 and 4195 of, and to amend the heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as introduced, Rubio. Pharmacy: clinics.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a knowing violation of its provisions a crime. Existing law authorizes a surgical clinic, as defined, that is licensed by the board to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the surgical clinic. Existing law prohibits a surgical clinic from operating without a license issued by the board. Existing law requires these surgical clinics to comply with various regulatory requirements and to maintain specified records. Existing law authorizes the board to inspect a surgical clinic at any time in order to determine whether a surgical clinic is operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a surgical clinic be licensed by the board but would require the clinics described above to be licensed in order to receive the benefits of these provisions. The bill would specify that the board is authorized to inspect only a clinic that is licensed by the board.

SB 1095 -2-

Because a knowing violation of these requirements by outpatient settings and ambulatory surgical centers would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known and may be cited as the California Outpatient Pharmacy Patient Safety and Improvement Act.

SEC. 2. The heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 14. Surgical-Clinics

SEC. 3. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

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26 27 (b) Notwithstanding any provision of this chapter, a-surgical elinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code clinic may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (b) (c). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and

-3- SB 1095

dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b)

1 2

(c) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c)

(d) No-surgical clinic shall-operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board.

(d) Any

- (e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.
- (f) Nothing in this section shall limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.
- SEC. 4. Section 4195 of the Business and Professions Code is amended to read:
- 4195. The board shall have the authority to inspect a clinic *that is licensed pursuant to this article* at any time in order to determine whether-a *the* clinic is, or is not, operating in compliance with this article and all other provisions of the law.
- SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because

SB 1095 —4—

- 1 the only costs that may be incurred by a local agency or school
- 2 district will be incurred because this act creates a new crime or
- 3 infraction, eliminates a crime or infraction, or changes the penalty
- 4 for a crime or infraction, within the meaning of Section 17556 of
- 5 the Government Code, or changes the definition of a crime within
- 6 the meaning of Section 6 of Article XIIIB of the California
- 7 Constitution.

SENATE CALIFORNIA LEGISLATURE

STATE CAPITOLROOM 2066
Sacramento, CA 95814
(916) 651-4016



MICHAEL J. RUBIO SENATOR, SIXTEENTH DISTRICT

SB 1095 – Fact Sheet Ambulatory Surgical Centers

DISTRICT OFFICES

2550 Mariposa Mall, Ste. 2016 Fresno, CA 93721 (559) 264-3070

1122 Truxtun Ave., Suite 100 Bakersfield, CA 93301 (661) 395-2620

What does SB 1095 do?

SB 1095 would expand the term "clinic" to include accredited or Medicare certified Ambulatory Surgical Centers (ASCs) in statute. This change would allow ASCs to obtain a license from the California Board of Pharmacy in order to purchase drugs at wholesale and safely store them within the facilities.

Background

ASCs are specialty clinics that perform same-day surgical care, including diagnostic and preventive procedures in an outpatient setting. As of 2007, there were more than twice as many outpatient surgeries performed as inpatient procedures in hospitals. The number of Medicare accredited ASCs have grown 8.3% annually due to the cost effective, high quality care that they provide. For example, studies show that Medicare would pay \$464 million dollars more per year if the procedures performed in ASCs were instead provided at hospitals.

In 2007, the California Court of Appeal ruled in *Capen v. Shewry* to prohibit the Department of Public Health from licensing ASCs that are either partially or fully owned by a physician, even if the physician-owned ASC is properly accredited and Medicare certified. This is problematic because approximately 90% of ASCs have some form of physician ownership. Furthermore, without licensure from the Department of Public Health, an ASC cannot obtain a pharmacy license.

Why is SB 1095 needed?

As a result of the *Capen v. Shewry* decision, physicians that own ASCs incur a significant liability by having to purchase drugs at retail prices. This bill provides physician-owned ASCs the proper licensing necessary to administer high quality care by allowing them to purchase certain drugs wholesale and storing them on site.

Support

California Ambulatory Surgery Association (Sponsor)





BILL NUMBER: SB 1095 VERSION: Introduced Feb. 16, 2012

AUTHOR: Rubio SPONSOR: Ca. Ambulatory Surgery Assn.

COMMITTEE RECOMMENDATION: Support if Amended

SUBJECT: Licensing: Clinics

Affected Sections: Amend Sections 4190 and 4195 of the Business and Professions Code

CURRENT STATUS: April 30, 2012 – Set for Hearing in Senate Appropriations

EXISTING LAW:

 Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale or maintain a commingled drug stock unless licensed by the California State Board of Pharmacy.

2. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:

- 1. Change the heading of Article 14 from "Surgical Clinic" to "Clinic"
- 2. Expand the definition of a "clinic" in Section 4190 to include:
 - Licensure by the Department of Public Health (DPH) under H&SC Section § 1204
 - An outpatient setting accredited by an approved agency as defined in H&SC § 1248 (Note: The MBC has four accreditation agencies: AAAHC, JCAHO, AAAAASF, and CMA IMQ)
 - An ambulatory surgical center certified by CDPH to participate in the Medicare Program
- 3. Authorize any of the clinics referenced above to purchase drugs at wholesale as specified.
- 4. Make licensure with the board optional.
- 5. Require notification to the board of any changes in ownership for any clinic licensed by the board.
- 6. Specify that nothing in the section will limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer or furnish drugs at a clinic.
- Specify that the board has authority to inspect any clinic that is licensed by the board.

SB 1095 Version: As Introduced Feb. 16, 2012

AUTHOR'S INTENT:

According to the author's office, SB 1095 would expand the term "clinic" to include accredited or Medicare certified Ambulatory Surgical Centers (ASCs) and would allow these ASCs to obtain a license from the board so that they can purchase drugs at wholesale. This measure is intended to provide a solution for clinics seeking board licensure following *Capen v. Shewry* which prohibited CDPH from issuing licenses to surgical clinics that were either partially or fully owned by a physician(s). Also according to the author, approximately 90 percent of ASCs have some form of physician ownership.

FISCAL IMPACT:

The initial application fee for a clinic license is \$400; annual renewal is \$250. Any increase in staff processing of applications would be offset by the application/renewal fees.

The board would require one additional Board Inspector to inspect new applicant/facilities and to conduct annual inspections of those clinics to ensure the compliance with Pharmacy laws and regulations. Personnel costs for one Board Inspector would be \$164,000 per fiscal year.

Capen v. Shewry (2007) 155 Cal.App.4th 378, 384-385

In response to a lawsuit that the California Department of Public Health was involved in regarding the regulation of a physician-owned ambulatory surgical clinic, several legislative remedies have been offered. Past remedies have generally expanded the conditions for licensure to allow the board to license surgical clinics that participate in the Medicare Program as well as those that were accredited by an approved agency. A summary of the lawsuit is provided below.

The California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to "...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as "surgical clinics" within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the "Capen decision," the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the ruling, the California State Board of Pharmacy could no longer issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

PREVIOUS LEGISLATION

AB 847 (Lowenthal) was significantly similar to SB 1095. The board had an Oppose Unless Amended position, stating that board licensure should be required. The measure died in ASM Committee on Health without being heard.

AB 2292 (Lowenthal) of 2010 contained provisions that would have expanded the conditions under which the board can issue a clinic license including surgical clinics licensed by the Department of Public Health, those certified to participate in the Medicare Program and those accredited by an approved agency. The board had a support position on this bill that was subsequently vetoed by Governor Schwarzenegger with the following veto message.

"This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

AB 1574 (Plescia) of 2008 would have expended the board's licensing authority to issue a (surgical) clinic permit to clinics that are Medicate certified or accredited by a recognized accreditation agency, require the board to perform inspections within 120 days of issuing a clinic license (and at least annually thereafter), and establish a self-assessment requirement. AB 1574 was vetoed by the Governor who stated that the bill failed to address the larger issue concerning the Capen v. Shewry ruling. The board had a Support position on this bill.

AB 2122 (Plescia) of 2008 would have required surgical clinics to meet prescribed licensing requirements and standards, including compliance with Medicare conditions of participation, and also contained provisions nearly identical to those proposed in AB 1574. AB 2122 died in Assembly Appropriations Committee. The board did not have a position on this bill.

AB 543 (Plescia) of 2007 also would have required surgical clinics to meet specified operating and staffing standards, to limit surgical procedures, as specified, and to develop and implement policies and procedures consistent with Medicare conditions of participation, including interpretive guidelines. AB 543 was vetoed by the Governor who stated that the bill did not establish appropriate time limits for performing surgery under general anesthesia,

inappropriately restricted administrative flexibility, and created fiscal pressure during ongoing budget challenges. The board had a Support position on this bill.

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner." The board had no position on this bill.

COMMENTS:

Following *Capen*, the board has consistently supported measures that allowed the board to expand its licensing of clinics to also include accredited outpatient settings (as specified), or to those that are Medicare certified.

Board licensure allows a clinic to purchase drugs at wholesale and allows for a common drug supply from which prescribers may dispense in amounts to meet the patient's needs for a 72 hour period. Equally important is the regulatory oversight to ensure that a clinic complies with applicable laws and regulations related to drug distribution, to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. This includes the requirement that a clinic have a professional director and the requirement to retain a consulting pharmacist who is responsible for approving the policies and procedures in conjunction with the director.

SEC.3 (starting on p. 2. line 12)

This bill would allow expand the definition of a "clinic" to include all of the following:

- A surgical clinic licensed per H&SC 1204 (b)(1) [these are licensed by CDPH/current law]
- An outpatient setting accredited by an accreditation agency, as defined at H&SC 1248 [this
 includes in vitro fertilization clinics]
- An ambulatory surgical center that is Medicare certified

SB 1095 makes this licensure permissive – not mandatory. This would be the case even for surgical clinics that are currently licensed by the board. For those entities that are not required by to be licensed by the Department of Public Health – and for those or others who would not seek licensure from the board – there may be a lack of regulatory oversight of a clinic's drug stock to ensure it is consistent with the promotion and protection of the health and safety of the public.

SEC.3 (starting at p. 3, line 15)

SB 1095 would amend existing subdivision (c) of Section 4190 to strike the requirement that a surgical clinic be licensed by the board. The board has consistently supported measures that allow the board to expand its authority to license clinics. The board, however, has also opposed provisions that make board licensure optional (AB 847).

SEC.3 (p. 3, line 29)

SB 1095 seeks to amend Section 4190 to add a subdivision (f) which would re-state the right of a physician and surgeon to dispense drugs as provided in B&PC Section 4170. Board staff feels this amendment is unnecessary. B&PC 4170 stands as current law. To say "Nothing in this section shall limit..." could cause concern that drug distribution in a clinic may not be limited to an amount needed to meet the patient's needs for a 72-hour period.

SEC.4 (starting on p. 3, line 35)

SB 1095 would amend Section 4195 to specify that the board shall have the authority to inspect only those clinics that are licensed by the board. Should the board feel that board licensure for these clinics be mandatory, these amendments would not be necessary.

COMMITTEE DISCUSSION

The Legislation and Regulation Committee discussed the measure on April 24, 2012, and is recommending a position of **Support if Amended.** The sponsor agreed to work the board to try and resolve issues of concern.

SUPPORT/OPPOSITION

According to the author, the following entities support SB 1095 (as of 4/3/12):

Ca. Ambulatory Surgery Association (sponsor) AmSurg Corp

Advanced Eye Surgery Center Antelope Valley Surgery Center

Airport Endoscopy Center ASD Management

Aspen Surgery Center
Brentwood Surgery Center
Carlsbad Surgery Center

Central California Endoscopy Center

Coast Surgery Center East Bay Endosurgery El Camino Surgery Center Glendale Eye Surgery Center

Glendora Digestive Disease Institute

Golden Triangle Surgicenter
Hacienda Surgery Center
Hope Square Surgical Center
Inland Surgery Center
La Jolla Endoscopy Center
Millennium Surgery Center

Monterey Peninsula Surgery Centers Monterey Peninsula Surgery Centers

National Surgical Hospitals North Coast Surgery Center Oasis Surgery Center Orthopaedic Surgery Center

OtayLakes Surgery Center

Outpatient Surgery Center of La Jolla Pain Diagnostic and Treatment Center

Parkway Endoscopy Center
Physicians Plaza Surgical Center
Pleasanton Surgery Center
Rancho Bernardo Surgery Center
Redding Endoscopy Center
Riverside Surgery Center
Roseville Surgery Center
San Luis Obispo Surgery Center

San Luis Obispo Surgery Center
San Mateo Surgery Center
Skyway Surgery Center
Southwest Surgical Center
Surgery Center of Santa Monica
Surgery Center of the Pacific
Surgical Care Affiliates

Temecula Valley Endoscopy Center Templeton Endoscopy Center The Oaks Surgery Center

The Surgery Center of Santa Rosa

United Surgical Partners

Valley Digestive Health Center

Opposition:

None known as of 4/16/2012

HISTORY:

2012

Apr. 9 From committee (SEN BP&ED): Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (April 9). Re-referred to Com. on APPR.

Mar. 21 Set for hearing April 9.

Mar. 1 Referred to Com. on B., P. & E.D.

Feb. 17 From printer. May be acted upon on or after March 18.

Feb. 16 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Negrete McLeod

February 24, 2012

An act to amend Sections 1241 and 4052.4 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, as introduced, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This bill would exempt a community pharmacy that solely provides certain tests classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1241 of the Business and Professions
- 2 Code is amended to read:

SB 1481 -2-

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

- (b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:
- (1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.
 - (2) Public health laboratories, as defined in Section 1206.
- (3) Those that perform clinical laboratory tests or examinations for forensic purposes only.
- (4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.
- (5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.
- (6) Those that register with the State Department of Health Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:
- (A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.
- (B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care

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provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

- (C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.
- (D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.
- (E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.
- (F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.
- (7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.
- (8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

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(9) A community pharmacy that is providing only those tests identified in Section 1246.5, provided that both of the following requirements are satisfied:

- (A) The pharmacy obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.
- (B) The tests are performed by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.
- (c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Services.
- SEC. 2. Section 4052.4 of the Business and Professions Code is amended to read:
- 4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or paragraph (9) of subdivision (b) of Section 1241. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or paragraph (9) of subdivision (b) of Section 1241. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NO.: SB 1481 VERSION: I – Feb. 24, 2012

AUTHOR: Negrete McLeod Committee Recommendation: Support

SUBJECT: Clinical Laboratories: Community Pharmacies (CLIA Waived Tests)

Affected Sections: Amend Sections 1241 and 4052.4 of the Business and Professions Code

CURRENT STATUS:

On 4/9/12, passed out of SEN Committee on Business, Professions and Economic Development. Re-Referred to Senate Appropriations (as of 4/26/12, no hearing set in APPR)

EXISTING LAW:

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, Laboratory Field Services (CDPH-LFS), subject to certain exceptions. Health and Safety Code section 1246.5 specifies tests that may be conducted pursuant to that section. Those tests are approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test.

The provisions of Section 1241 of the Health and Safety Code applies to all clinical laboratories in California or those receiving biological specimens originating in California for the purpose of performing a clinical laboratory test, to all persons performing clinical laboratory tests, or engaging in clinical laboratory practice, with specified exceptions. Among those that the provisions of Section 1241 do not apply to, include emergency medical technicians and paramedics who perform blood glucose tests that are classified as waived under CLIA, so long as the provider obtains a valid certificate of waiver and complies with other requirements for the performance of waived tests under federal regulations.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests in a clinic, as specified. These tests include clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (see B&PC 4052.4).

The federal Centers for Medicare & Medicaid Services (CMS) grants CLIA Waivers to entities that conduct only those tests which are deemed 'waived' by CMS. These are tests which are determined to be so simple that there is little risk of error.

THIS BILL WOULD:

Exempt from the licensure and regulation of clinical laboratories a community pharmacy that provides specified tests that are classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA. This bill would make conforming changes to Section 4052.4 of the business and professions code, which currently authorizes a pharmacist to conduct these tests in specified settings.

AUTHOR'S INTENT:

According to the author, there is a growing need for consumers to have access to basic laboratory tests that are related to medication therapy. The New England Healthcare Institute states that "poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of \$290 billion per year in unnecessary health care spending. There are commercially available tests that can help patients and their medical providers monitor therapy and disease. With the results of these tests, appropriate adjustments to treatment can be made in a timely manner.

"Passage of this legislation will result in easier access to safe, simple, and economic tests – especially for low income individuals – les crowding in physicians' offices, and an improved ability of pharmacists to provide meaningful feedback to their patients when providing drug consultations required by law."

COMMENTS:

This bill would allow a pharmacist in a community pharmacy to perform only specific tests which are "waived" by CLIA – the same tests that a pharmacist is currently authorized to conduct in a clinic setting, pursuant to Section 4052.4. The California Legislature has declared that the practice of pharmacy is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

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BILL HISTORY

2012

Apr. 9 From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0. Page 3087.) (April 9). Re-referred to Com. on APPR.

Mar. 27 Set for hearing April 9.

Mar. 22 Referred to Com. on B., P. & E.D.

Feb. 27 Read first time.

Feb. 25 From printer. May be acted upon on or after March 26.

Feb. 24 Introduced. To Com. on RLS. for assignment. To print.
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AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

AB 377 -2 -

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, but would impose limitations on the services provided by a centralized hospital pharmacy. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- SECTION 1. Section 4029 of the Business and Professions Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets

-3- AB 377

all of the requirements of this chapter and the rules and regulations of the board.

- (b) A hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital, in either another physical plant on the same premises or on a separate premises, located within a-100 mile 100-mile radius of the hospital, that is regulated under a hospital's license. A centralized hospital pharmacy may only provide pharmaceutical services to its own patients who are either admitted or registered patients of a hospital within the same health care system. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.
- (c) Any unit-dose medication produced by a hospital pharmacy under common ownership, as described in Section 4033, shall be barcoded to be readable at the patient's bedside.
- (d) A hospital pharmacy may prepare and store a limited quantity of unit-dose medications in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of patients of the hospital based on a documented history of prescriptions for that patient population.
- (e) Nothing in this section shall limit the obligation of a hospital pharmacy, hospital, or pharmacist to comply with all applicable federal and state laws.
- SEC. 2. Section 4033 of the Business and Professions Code is amended to read:
- 4033. (a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.
- (2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for the purpose of dispensing or administering the drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or

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repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change.

- (3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.
- (b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third-party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.
- SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.



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Assembly Bill 377 (Solorio) Reducing Medication Errors in Hospitals

Background:

Medication errors in hospitals have been a public policy concern for years, and despite on-going efforts, the incidence of these errors remains unacceptably high. Studies show that the ability of hospitals to deliver barcoded unit doses to patients' bedsides can effectively reduce the incidence of medication errors. Unfortunately, the cost of this technology is prohibitively expensive, because current law mandates that only an on-site hospital pharmacy can prepare drugs for inpatients.

Hospitals wanting to implement a bar-coded unit dose system face both technological and legal impediments. In most circumstances, it is simply too expensive to invest in this technology on a per-hospital basis, even for large hospitals. Clearly, patient-safety modernization is beyond the practical reality for virtually all hospitals.

Problem:

Current law requires medications for inpatients to be prepared by a licensed pharmacy located on the hospital's premise. This limits the opportunity to invest in expensive technology that would improve efficiency and enhance patient safety. In addition, certain medications, notably injectable compounds that are prepared within the hospital pharmacy, would come under federal "manufacturing" regulations if prepared off-site unless there is a state regulatory law to govern this activity.

Legislative Solution:

Assembly Bill 377 would establish a licensing category for a "centralized hospital pharmacy" and set parameters governing these pharmacies. Specifically, the bill would authorize a centralized pharmacy to deliver bar-coded unit dose medications to hospitals that are under common ownership or control and within a 100 mile geographic radius. It also would allow these pharmacies to prepare pill/capsule, as well as injectable and intravenous medications for inpatients at an offsite location.

This bill would amend the current definition of "manufacturer" to exclude pharmacies packaging drugs for distribution or administration in a hospital. In addition, this bill would amend the definition of "hospital pharmacy" to allow an off-site pharmacy operating under a hospital's license to support the pharmacy needs of all its hospitals. The pharmacy activities authorized under this bill are the same activities that are currently performed in individual pharmacies on hospital premises.

Contact:

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Lead Proponents:

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CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 377 VERSION: As Amended April 14, 2011

AUTHOR: Solorio SPONSOR: California Hospital Association and

California Society of Health Systems Pharmacists

BOARD POSITION: Support if Amended (May 2011)

SUBJECT: Pharmacies: Centralized Hospital Packaging

AFFECTED SECTIONS: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Last location: Senate Appropriations Committee (8/15/11).

Hearing postponed by committee.

EXISTING LAW:

1. Defines a hospital pharmacy as a pharmacy licensed by the board that is located inside a hospital as specified.

- Allows a hospital pharmacy to be located outside of the hospital building if the hospital
 pharmacy is on the California Department of Public Health's consolidated license and if the
 pharmacy is only providing pharmacy services to inpatients of the hospital.
- 3. Defines "manufacturer" and exempts compounding, as specified from the definition.

THIS BILL WOULD:

- 1. Specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius, which is regulated under a hospital's license.
- 2. Specify that these services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.
- 3. Specify that unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership must be bar-coded to be readable at the patient's bedside.
- 4. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
- 5. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for purposes of administering medication pursuant to a prescription order.
- 6. Require a pharmacy performing such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:

According to the author, "technology is now capable of providing hospitals with a method to deliver barcoded unit-doses to in-patients' bedsides. However, the cost of this technology renders it virtually impossible for hospitals to do within the structures of the current hospital pharmacy. In addition, because the new central pharmacy would serve multiple hospitals (though the hospitals are under

common ownership), currently lawful hospital pharmacy activities might run afoul of the manufacturing law." The author notes that the potential to finally and effectively address in-patient medication errors is greatly expanded by this proposal.

FISCAL IMPACT:

Board staff does not anticipate any significant impact. Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

Amendments to this measure clarify that the centralized pharmacy services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.

This proposal appears consistent with the board's mission statement "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." This proposal would allow a hospital to leverage existing technology to prepare unit-dose medications that include bar-coding technology that must be readable at the patient's bedside.

Recent Update

CSHP indicated that it anticipates amendments being incorporated into this measure in July 2012. According to CSHP, the amendments will address the board's concerns raised last year.

Background

Over the years the board has evaluated the issue of medication errors and reviewed materials and heard presentations from experts on what can be done to reduce such errors. Bar-coding technology has been identified as one tool that can be used to reduce medication errors. In 2004, the FDA established bar code label requirements for human drug and biological products (21 CFR Parts 201, 606, et al.) The FDA included in its guidance document, "Bar codes will allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This new system is intended to help reduce the number of medication errors that occur in hospitals and health care settings." (Hospitals are exempt from the FDA requirement to barcode unit-dose packages.) In 2004, the FDA also noted that hospitals that were using bar-coding at that time avoided 50% of the adverse drug events caused by errors in the distribution and administration of prescriptions.

A summary from a study published in 2006, "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy, Poon et. Al," included:

"...our study results suggest that bar code technology in a hospital pharmacy may substantially reduce serious dispensing errors. In particular, it may target several types of dispensing errors that may frequently harm patients, including wrong medication, wrong dose, or wrong formulation errors. However, the scanning technology should be configured to ensure that all doses are scanned at least once during the dispensing process. If optimally configured, this technology may be an important addition to the medication safety armamentarium." Further, a portion of the discussion from this study also included:

"The rates of target dispensing errors and potential ADEs substantially decreased after the implementation of bar code technology: The target dispensing error rate decreased by 85%, and the rate of all dispensing-related potential ADEs decreased by more than 60%."

As this measure does not currently specify the requirements of the bar-coding, the board may want to consider offering an amendment to clarify what information should be contained within bar-code. The board may want to consider the FDA requirement elements established in 21 CFR Parts 201, 606, et al.

PRIOR BOARD DISCUSSION and ACTION:

During the May 2011 Board Meeting, the board spoke in support of this measure. Technical issues were raised by counsel during this discussion about some clarity issues. As a result, the board voted to establish a Support if Amended position. Following the meeting, board staff conveyed the board's position to CSHP and discussed the changes being sought.

PREVIOUS LEGISLATION:

The board previously supported AB 1370 (Solorio, 2009) which contained provisions similar to this bill.

The board previously supported AB 2077 (Solorio, 2010) which contained provisions similar to this bill. This bill was vetoed by the governor.

"This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

SUPPORT/OPPOSITION:

Support:

California Hospital Association (sponsor)
California Pharmacists Association
Antelope Valley Hospital
California Society of Health-System Pharmacists
Mercy General Hospital
Sharp
St. Joseph's Medical Center, Pharmacy Department
Touro University, College of Pharmacy
Individual Pharmacists

Opposition:

None of file

HISTORY:

Date Action

2011

Aug. 15 In committee: Hearing postponed by committee.

July 5 In committee: Set, second hearing. Hearing canceled at the request of author.

- June 21 In committee: Set, first hearing. Hearing cancelled at the request of author.
- June 14 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes. 0.) (June 13). Re-referred to Com. on APR.
- May 26 Referred to Com. on B., P. & E.D.
- May 12 In Senate. Read first time. To Com. on RLS. for assignment.
- May 12 Read third time. Passed. Ordered to the Senate. (Ayes 70. Noes 0. Page 1356.)
- May 9 Read second time. Ordered to consent calendar.
- May 5 From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 4).
- Apr. 26 From committee: Do pass and re-refer to Com. on APPR. With recommendation: to consent calendar. (Ayes 9. Noes 0.) (April 26). Re-referred to Com. on APPR.
- Apr. 25 Re-referred to Com. on B., P. & C.P.
- Apr. 14 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
- Apr. 12 From committee: Do pass and re-refer to Com. on B., P. & C.P. (Ayes 19. Noes 0.) (April 12). Re-referred to Com. on B., P. & C.P.
- Mar. 7 Referred to Coms. on HEALTH and B., P. & C.P.
- Feb. 15 From printer. May be heard in committee March 17.
- Feb. 14 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 27, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1896

Introduced by Assembly Member Chesbro

February 22, 2012

An act to amend the heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of, and to add Section 719 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1896, as amended, Chesbro. Tribal health programs: health care practitioners.

Under existing federal law, licensed health professionals employed by a tribal health program are required to be exempt, if licensed in any state, from the licensing requirements of the state in which the tribal health program performs specified services. A tribal health program is defined as an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Indian Health Service.

Existing law provides for the licensure and regulation of health care practitioners by various healing arts boards within the Department of Consumer Affairs.

This bill would codify that federal requirement by specifying that a person who is licensed as a health care practitioner in any other state and is employed by a tribal health program is exempt from any state licensing requirement with respect to acts authorized under the person's license where the tribal health program performs specified services.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

AB 1896 -2-

The people of the State of California do enact as follows:

SECTION 1. The heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of the Business and Professions Code is amended to read:

Article 10. Federal Personnel and Tribal Health Programs

- SEC. 2. Section 719 is added to the Business and Professions Code, to read:
- 719. (a) A *person who is licensed as a* health care practitioner *in any other state and is* employed by a tribal health program, as defined in Section 1603 of Title 25 of the United States Code, shall be exempt from any licensing requirement described in this division *with respect to acts authorized under the person's license* where the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. Sec. 450 et seq.).
- (b) For purposes of this section, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under this division or any initiative act referred to in this division the law of any other state.

AB 1896 (CHESBRO) Affordable Care Act Alignment

Background

California's Tribal Health Programs are not-for-profit medical practices and medical research groups that provide primary care services, general dentistry, substance abuse counseling and mental health services. In California we have 31 Tribal Health Programs that operate 57 ambulatory clinics in primarily rural regions. These critically important safety net facilities serve over 130,000 American Indian/Alaska Native patients and multiple Medi-Cal patients on an annual basis.

Problem

Tribal Health Clinics have a severe shortage of physicians in underserved and rural areas. This lack of doctors places an undue burden on the existing provider network, risks a high turnover rate for current doctors, disrupts the continuity of care and challenges patient safety. This makes it difficult to recruit and retain health care providers willing to live and work in remote locations and overworked providers in the Indian health care delivery system with quickly developed burnout. The problem is especially acute in remote tribal and other rural communities, which lack the usual conveniences with which providers are familiar.

Solution

To address the problem of staff shortages in Tribal Health Clinics, the U.S. Congress adopted language in the Federal Affordable Care Act. This act allows health care providers employed by Tribal Health Programs to work in States without licensure as long as they hold a license from another State. AB 1896 will align the Federal Affordable Care Act provisions with California State statute and codifying Federal Law.

The bill is important to help address a longstanding and increasingly severe shortage of physicians in Tribal Health Clinics that exists in underserved, rural areas. The goal is to increase the number of doctors practicing in rural areas resulting in increased health care access for communities served by Tribal Health Clinics.

Contact

Robb Layne
Office of Assemblymember Chesbro
(916) 319-2001

Mark LeBeau California Rural Indian Health Board (916) 929-9761

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 1896 VERSION: Amended March 27, 2012

AUTHOR: Chesbro SPONSORS:

COMMITTEE RECOMMENDATION:

SUBJECT: Healing Arts: Tribal Health Programs: Healthcare Practitioners

Affected Sections: Amends the heading of Article 10, and Amends Section 719 of the

Business and Professions Code

Current Status: 4/18/12 – On ASM Third Reading File

EXISTING LAW:

 Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.

- 2. Allows a hospital to enter into an agreement with the Armed Forces of U.S. to authorize a physician and surgeon, physician assistant, or registered nurse to provide medical care in the hospital under specified conditions, including that the practitioner holds a valid license in good standing to provide medical care in the D.C. or any state or territory of the U.S., and that the practitioner registers with the appropriate California licensing board, as specified.
- Under current federal law, a heath care professional, as defined, is able to practice his
 or her profession in any state or territory without licensure by that state if he or she has
 a current license to practice the profession and is performing authorized duties for the
 Department of Defense.
- 4. Under current federal law, the Patient Protection and Affordable Care Act (PPACA), licensed health professionals employed by a tribal health program shall be exempt, if licensed in any state, from the licensing requirement of the state in which the tribal health program performs the services described in the contract or compact of the tribal health program under the ISDEAA.

THIS BILL:

- 1. Seeks to codify existing federal law into state law to specify that a health care professional employed by tribal health program is exempt from state licensure if that health care professional holds a license from another state.
- 2. Would defines "health care practitioner" to mean any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

AUTHOR'S INTENT:

According to the author, the bill is important to help address a longstanding and increasingly severe shortage of physicians in Tribal Health Clinics that exists in underserved, rural areas. The goal is to increase the number of doctors practicing in rural areas resulting in increased health care access for communities served by Tribal Health Clinics.

To address the problem of staff shortages in Tribal Health Clinics, the U.S. Congress adopted language in the Federal Affordable Care Act. This act would allow health care providers employed by Tribal Health Programs to work in States without licensure as long as they hold a license from another State. AB 1896 will align the Federal Affordable Care Act provisions with California State statute and codifying Federal Law.

COMMENTS:

If current federal law (the Patient Protection and Affordable Care Act) already exempts health care professionals that are employed by a tribal health program so long as they are licensed in another state, is it necessary to codify the provision in State law?

SUPPORT/OPPOSITION:

According to the ASM Committee on Business, Professions and Consumer Protection

Support

California Rural Indian Health Board
California Rural Indian Health Board, Tribal Governments Consultation Committee
Oppose

HISTORY:

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Date Action
2012

Apr. 12 Read second time. Ordered to third reading.

Apr. 11 From committee: Do pass. (Ayes 9. Noes 0.) (April 10).

Mar. 28 Re-referred to Com. on B., P. & C.P.

Mar. 27 In committee: Set, first hearing. Hearing canceled at the request of author. From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.

Mar. 8 Referred to Com. on B., P. & C.P.

Feb. 23 From printer. May be heard in committee March 24.

Feb. 22 Read first time. To print.
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Introduced by Assembly Members Block, Butler, and Cook

February 22, 2012

An act to add Section 115.5 to the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1904, as introduced, Block. Professions and vocations: military spouses: temporary licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. Under existing law, licensing fees imposed by certain boards within the department are deposited in funds that are continuously appropriated.

This bill would authorize a board within the department to issue a temporary license to an applicant who, among other requirements, holds an equivalent license in another jurisdiction, as specified, and is married to, or in a legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. The bill would require a board to expedite the process for issuing these temporary licenses. The bill would require the applicant to pay any fees required by the board and would require that those fees be deposited in the fund used by the board to administer its licensing program. To the extent that the bill would

AB 1904 — 2 —

increase the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 115.5 is added to the Business and 2 Professions Code, to read:
 - 115.5. (a) A board within the department may issue a temporary license to an applicant who meets all of the following requirements:
 - (1) Submits an application in the manner prescribed by the board.
 - (2) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.
 - (3) Holds a current license in another state, district, or territory of the United States with the requirements that the board determines are substantially equivalent to those established under this code for that occupation.
 - (4) Has not committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed.
 - (5) Has not been disciplined by a licensing entity in another jurisdiction and is not the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.
 - (6) Pays any fees required by the board. Those fees shall be deposited in the applicable fund or account used by the board to administer its licensing program.
 - (7) Submits fingerprints and any applicable fingerprinting fee in the manner required of an applicant for a regular license.
 - (b) A board shall expedite the procedure for issuing a temporary license pursuant to this section.
- 31 (c) A temporary license issued under this section shall be valid 32 for 180 days, except that the license may, at the discretion of the

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- board, be extended for an additional 180-day period on application
 of the license holder.
- 3 (d) A board may adopt regulations necessary to administer this
- 4 section.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 1904 VERSION: As Introduced February 22, 2011

AUTHOR: Block, Butler and Cook SPONSOR:

COMMITTEE RECOMMENDATION: SUPPORT

SUBJECT: Military Spouses: Temporary Licenses

Affected Sections: Add Section 115.5 to the Business and Professions Code

CURRENT STATUS: (4/18/12) In Assembly Appropriations. Referred to

ASM Appropriations Suspense File

EXISTING LAW:

1. Allows for the regulation of various business and professions within the Department of Consumer Affairs

2. Defines the licensing requirements for the board to issue a license.

THIS BILL WOULD:

- 1. Allow the board to issue a temporary permit to an applicant that submits an application, fees and fingerprints and satisfies specified requirements including proof of licensure in good standing in another state with similar requirements.
- 2. Require the board to expedite the processing for purposes of issuing a temporary license.
- 3. Specifies that the temporary license will be valid for 180 days and may be extended for an addition 180-day period.
- 4. Authorize the board to promulgate regulations necessary to implement the provisions.

AUTHOR'S INTENT:

The author's office states, "State licensing and certification requirements are intended to ensure that practitioners meet a minimum level of competency. Because each state has it own licensing requirements, threes requirements often vary greatly across state lines. Consequently, the lack of license portability...can impose significant administrative and financial burdens on licensed professionals when they move across state lines."

AB 1904 Version: As Introduced

FISCAL IMPACT:

Staff anticipates that the boards to implement these provisions would generally be one-time costs associate with development of the necessary regulations and application forms. In addition the board would incur programming costs for the computer system. The department estimates this cost to be almost \$130,000? for each license type prior to the board's implementation of the new BreEZe computer system. After the transition to the new system the costs would go down significantly.

COMMENTS:

Board staff anticipates that the two primary license types would be impacted - - pharmacist and pharmacy technician. According to the Survey of Pharmacy Law prepared by the National Associations of Boards of Pharmacy education and experience requirements do not vary greatly. The most significant difference in pharmacist licensure requirement is the board's CPJE examination. There would be a cost impact to modify the department's licensing system to establish a new license type.

RELATED LEGISLATION:

AB 1588 (Atkins) will require the board to waive a renewal fee and continuing education requirements for a military reservist that is called to active duty.

SUPPORT/OPPOSITION

Support

Department of Defense State Liaison Office

Opposition

None on file

HISTORY:

Date	Action
Apr. 18	In committee: Set, first hearing. Referred to APPR. suspense
	file.
Mar. 27	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9.
	Noes 0.) (March 27). Re-referred to Com. on APPR.
Mar. 8	Referred to Com. on B., P. & C.P.
Feb. 23	From printer. May be heard in committee March 24.
Feb. 22	Read first time. To print.

Bill Analysis: AB 1904 as introduced

Introduced by Senator Price

February 22, 2012

An act to add Part 12.2 (commencing with Section 15910) to Division 3 of Title 2 of, *and to repeal Section 15923 of*, the Government Code, relating to the Centralized Intelligence Partnership Act.

LEGISLATIVE COUNSEL'S DIGEST

SB 1185, as amended, Price. Centralized Intelligence Partnership Act.

Existing law requires various state entities, including, but not limited to, the State Board of Equalization, the Franchise Tax Board, and the Department of Justice, to enforce laws relating to the taxation and legal operation of businesses throughout the state under their respective jurisdictions.

This bill would create a multiagency partnership consisting of specified state entities, to be known as the Centralized Intelligence Partnership, to collaborate in combating illegal underground operations by, among other activities, providing a central intake process and organizational structure, with an administrator and support staff, to document, review, and evaluate data and complaints. This The bill would create an advisory committee, comprised of one representative from each entity participating in the partnership, to provide guidance on the activities and operations of the partnership. This The bill would require the advisory committee to the partnership to determine the appropriate agency to house the processing center for the partnership. The bill would authorize duly authorized representatives of members of the partnership to exchange information for the purpose of

SB 1185 -2-

investigating illegal underground operations. The bill would require the partnership, starting on or before July 1, 2014, to annually report to the Legislature and entities—belonging—to participating in the partnership on its activities. The bill would require an additional report to be filed with the Legislature by December 1, 2018, to include the number of complaints received by the partnership and cases investigated or prosecuted, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the 2 following:

- (a) According to the Employment Development Department's analysis of findings made by the Internal Revenue Service, the underground economy in California is estimated to be between \$60 billion sixty billion dollars (\$60,000,000,000) and \$140 billion one hundred forty billion dollars (\$140,000,000,000) each year.
- (b) According to the State Board of Equalization, an average of \$8 billion eight billion dollars (\$8,000,000,000) in corporate, personal, and sales and use taxes goes uncollected in California each year, with unreported and underreported economic activity responsible for the vast majority of that total.
- (c) The underground economy hurts all Californians. Revenues to support government services are lost, workers are forced to go without basic employment protections, and legitimate businesses are confronted with unfair competition. Furthermore, the presence of the underground economy allows human traffickers to operate and victimize individuals who are trapped into forced labor conditions. Regrettably, California is reported to be one of the top four human trafficking destination states in the United States.
- (d) Since the activities of many operating in the underground economy span across multiple jurisdictions, various joint agency enforcement efforts have been undertaken to combat the underground economy, including, but not limited to, the creation of the Joint Enforcement Strike Force *on the Underground Economy* in 1993, and the creation of the Economic and Employment Enforcement Coalition in 2005. Furthermore, various individual agency efforts have been created, including, but not

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limited to, the State Board of Equalization's Statewide Compliance 1 2 and Outreach Program and the Contractors' State License Board's 3 Statewide Investigative Fraud Team. Thus, investigative 4 collaboration among state agencies is not a new concept in 5 California. Many collaborative efforts are already under way, 6 pursuant to which investigators periodically meet to discuss current 7 investigations, collaborate to conduct sting operations, and develop 8 best practices policies.

(e) Despite significant statewide efforts, California continues to lose billions of dollars in annual revenue due to the underground economy.

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- (f) The Legislature intends this act to enhance existing efforts to combat the underground economy by institutionalizing collaboration among state agencies through a Centralized Intelligence Partnership that acquires relevant data for collaborative data analysis, economic threat assessment, strategic planning, and provides a referral tracking and value-added referral disbursement process to monitor the progress and measure the success of the partnership activities. This collaborative effort to combat the underground economy will, in turn, further aid the state in its progress toward preventing human trafficking. The Legislature recognizes that the state needs to comprehensively address the underground economy and capitalize on each agency's enforcement efforts and investigative resources by creating the Centralized Intelligence Partnership. A key element of this effort is to authorize and facilitate data and intelligence sharing among the Centralized Intelligence Partnership and state agencies. It is the intent of the Legislature in enacting this act to focus on the criminal and civil prosecution of those operating in the underground economy in flagrant violation of the law. Businesses that are in compliance with state employment, safety, licensing, and tax laws that are found to have committed minor or inadvertent violations of existing law are to be addressed through other administrative procedures.
- (g) It is the intent of the Legislature that this act be part of ongoing efforts by the Legislature to combat the underground economy in this state through legislation.
- SEC. 2. Part 12.2 (commencing with Section 15910) is added to Division 3 of Title 2 of the Government Code, to read:

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PART 12.2. CENTRALIZED INTELLIGENCE PARTNERSHIP 2 ACT 3 4 15910. This part shall be known, and may be cited, as the Centralized Intelligence Partnership Act. 5 15912. (a) The Centralized Intelligence Partnership is hereby 6 7 established in state government. 8 (b) For purposes of this part, the term "partnership" shall refer to the Centralized Intelligence Partnership. 15914. (a) The partnership shall include all of the following 10 state entities: 11 12 (1)13 (a) California Health and Human Services Agency. 14 (b) Department of Consumer Affairs. 15 16 (3)17 (c) Department of Industrial Relations. 18 19 (d) Department of Insurance. 20 (5) 21 (e) Department of Justice. 22 23 (f) Department of Motor Vehicles. 24 (7)25 (g) Employment Development Department. 26 27 (h) Franchise Tax Board. 28 (9) 29 (i) State Board of Equalization. 30 (b) The Centralized Intelligence Partnership may include any other state or local entity that chooses to participate. 31 32 (a) The advisory committee to the Centralized 33 Intelligence Partnership is hereby established to provide guidance 34 to, and advice on, the activities and operations of the partnership. (b) The advisory committee is comprised of one representative 35 from each of the entities-participating in the partnership. Each 36 37 representative shall be appointed by the head of the entity 38 participating in the partnership and serve at the pleasure of the 39 appointing authority.

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(c) The advisory committee shall meet as needed but at least quarterly to conduct its business.

- 15918. (a) To serve the best interests of the state by combating the underground economy, the partnership shall do all of the following to combat illegal underground operations:
- (1) Provide a central intake process and organizational structure to document, review, and evaluate data and complaints.
- (2) Establish a processing center to receive and analyze data, share complaints, and research leads from the input of each impacted agency, including, but not limited to, federal and local law enforcement agencies.
- (3) Provide participating and nonparticipating agencies with value-added investigative leads where collaboration opportunities exist for felony-level criminal investigations, including, but not limited to, referring leads to agencies with appropriate enforcement jurisdiction.
- (4) Provide that each participating and nonparticipating agency retain jurisdictional authority over whether to pursue partnership strategies or collaborative investigative leads based upon the direction of their respective governing structures or available resources.
- (5) Document and provide intake data analysis, analytic data findings, referrals, collaborative opportunities, outcomes, emerging evasion trends, lessons learned, as well as additional enforcement, administrative, and legislative opportunities.
- (b) The scope of activities and projects undertaken by the partnership shall be consistent with the amount of funds appropriated by the Legislature.
- (c) The Department of Justice advisory committee to the partnership shall determine the appropriate agency to house the processing center for the partnership.
 - (d) The partnership may hire an administrator and staff.
- 15920. Notwithstanding any other law, duly authorized representatives of members of the partnership may exchange intelligence, data, documents, information, complaints, or lead referrals for the purpose of investigating illegal underground operations. Information exchanged pursuant to this section shall retain its confidential status.
- 15920. Duly authorized representatives of members of the partnership may exchange intelligence, data, documents,

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1 information, complaints, or lead referrals for the purpose of

- 2 investigating illegal underground operations. Any member or
- 3 ex-member of the partnership, any agent employed by any member
- 4 of the partnership, or any person who has at any time obtained
- 5 such knowledge from any of the foregoing partners or persons,
- 6 shall not divulge, or make known in any manner not provided by
- 7 law, any of the confidential information received by, or reported
- 8 to, the partnership. Information exchanged pursuant to this section
- 9 shall retain its confidential status and shall remain subject to the confidentiality provisions contained in the following provisions:
 - (a) Department of Consumer Affairs: Section 30 of the Business and Professions Code and Section 56.29 of the Civil Code.
 - (b) Department of Justice: Section 11183 of the Government Code.
 - (c) Department of Motor Vehicles: Sections 1808.2, 1808.4, 1808.5, 1808.6, 1808.21, 1808.24, and 12800.5 of the Vehicle Code.
 - (d) Employment Development Department: Sections 1094 and 1095 of the Unemployment Insurance Code.
- 20 (e) Franchise Tax Board: Sections 19542, 19542.1, and 19542.3 of the Revenue and Taxation Code.
 - (f) State Board of Equalization: Section 15619 of the Government Code, Section 42464.8 of the Public Resources Code, and Sections 7056, 7056.5, 8255, 9255, 9255.1, 30455, 38705, 38706, 43651, 45981, 45982, 45983, 45984, 46751, 50159, 50160, 50161, 55381, 60608, and 60609 of the Revenue and Taxation Code.
 - 15922. On or before July 1, 2014, and annually thereafter, the partnership shall report on its activities and accomplishments to the Legislature and each—participating member entity in the partnership.
 - 15923. (a) The partnership shall submit to the Legislature on or before December 1, 2018, a report that includes, but is not limited to, the following information:
 - (1) The number of leads or complaints received by the partnership.
- 37 (2) The number of cases investigated or prosecuted through civil action or criminal prosecution.
- 39 *(3) Recommendations for modifying, eliminating, or continuing* 40 *the operation of any or all of the provisions of this part.*

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- 1 (b) This section shall remain in effect only until January 1, 2020,
- and as of that date is repealed, unless a later enacted statute, that
- 3 is enacted before January 1, 2020, deletes or extends that date.



SB 1185 - PRICE TACKLING THE UNDERGROUND ECONOMY: CENTRALIZED INTELLIGENCE PARTNERSHIP ACT

SUMMARY

Senate Bill 1185 (Price) seeks to address the problems caused by California's underground economy. This legislation establishes a multiagency collaboration, which will be known as the Centralized Intelligence Partnership (CIP). The CIP will facilitate consumer complaints, perform research that will assist in the recapturing of unreported taxes, aide in exposing employers who exploit workers and assist in efforts to investigate and prosecute violations.

The CIP will increase California's revenues by and expediting investigations reducing prosecution costs through multijurisdictional agency collaboration. The partnership would include the following state entities: Board of Equalization, Franchise Tax Board, Health and Human Services Agency, Department of Consumer Affairs, Department of Industrial Department Relations. of Insurance. Department of Justice, Department of Motor Vehicles, and the Employment Development Department.

BACKGROUND

The underground economy refers to those individuals and businesses that deal in cash and/or use other schemes to conceal their activities, identities, and true tax liabilities from government licensing, regulatory, and taxing agencies. Activities that occur in the

underground economy include the sale or transfer of illegal goods, such as pirated music or movies, counterfeit pharmaceutical drugs, clothing, accessories, weapons, tax evasion or fraud, and untaxed tobacco products or alcohol.

The underground economy hurts innovation, creative and economic development in California. The California Board of Equalization estimates that \$8 billion in corporate, personal, and sales and use taxes go uncollected in California each year, with unreported and underreported economic activity responsible for the vast majority.

Most importantly, the underground economy hurts all Californians. This uncollected revenue is needed to provide vital public services such as education, public safety and infrastructure improvements.

SUPPORT

Board of Equalization (Sponsor)

DO YOU SUPPORT SB 1185?

Please send a letter of support to: Senator Curren Price State Capitol Rm. 2052, Sacramento, CA 95814

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: SB 1185 VERSION: As Amended April 9, 2012

AUTHOR: Price SPONSOR: State Board of Equalization

RECOMMENDED BOARD POSITION: None

SUBJECT: Centralized Intelligence Partnership Act

AFFECTED SECTIONS: An act to add Part 12.2 (commencing with Section 15910) to Division 3

of Title 2 of, and to repeal Section 15923 of, the Government Code

CURRENT STATUS: Referred to Senate Appropriations

EXISTING LAW:

 Establishes several different government entities responsible for oversight, regulation and enforcement of various businesses and individuals doing business in California including:

- a. California Health and Human Services Agency
- b. Department of Consumer Affairs
- c. Department of Industrial Relations
- d. Department of Insurance
- e. Department of Justice
- f. Department of Motor Vehicles
- g. Employment Development Department
- h. Franchise Tax Board
- i. State Board of Equalization
- B&PC Section 110 specifies that the department (DCA) has possession and control of all records etc. held for use by all bodies, offices and officers comprised within the department.

THIS BILL WOULD:

- 1. Create the Centralized Intelligence Partnership consisting of the above agencies and establish an advisory committee with membership from each agency.
- 2. Specify that the advisory committee is charged with combating the underground economy and specifies the general scope of the committee's process.
- 3. Allow for the sharing of information between the members of the advisory committee and provides that information shared via this process will retain is confidential status as authorized by law.
- 4. Establish reporting requirements for this advisory committee.
- 5. Establish a January 1, 2020 sunset date.

SB 1185 Version: As Amended April 9, 2012

AUTHOR'S INTENT:

The author's fact sheet indicates that this measure "seeks to address the problems caused by California's underground economy. This legislation establishes a multiagency collaboration, which will be known as the Centralized Intelligence Partnership (CIP). The CIP will facilitate consumer complaints, perform research that will assist in the recapturing of unreported taxes, aide in exposing employers who exploit workers and assist in efforts to investigate and prosecute violations."

COMMENTS:

Recent information received from the Board of Equalization indicates that this measure is silent in several areas to allow for flexibility in the establishment of the partnership. Once established, the partnership would most likely determine the scope of investigations that would be done under its purview. It is not the intent of this legislation to require all investigations initiated by the board to be evaluated and investigated through this partnership.

The board has working relationships with several other regulatory agencies including the Department of Public Health, Department of Health Care Services as well as local, state and federal enforcement agencies. Board inspectors participate in joint investigations on a fairly routine basis.

Both the department and board staff recommends that at minimum amendments be offered to the author's office to include specific reference to two Government Code sections that relate to access to board records.

FISCAL IMPACT:

Based on discussion with BOE, it is unclear the number of additional investigations the board would be involved in investigating. BOE estimates that it will realize a 120% increase in investigations.

According to the analysis prepared for the Senate Committee on Governmental Organization, BOE estimates an revenue increases of \$15M will be associated with these cooperative enforcement activities.

SUPPORT/OPPOSITION:

<u>Support</u>

Board of Equalization (sponsor)

California Association for Health Services at Home

California Building Industry Association

California Chamber of Commerce

California Grocers Association

California Healthcare Institute

California Manufacturing and Technology Association

California Spa & Pool Industry Educational Council

California Statewide Law Enforcement Association

California Taxpayers Association

City of Carson

City of Gardena

Bill Analysis: SB 1185 as amended

City of Hawthorne
City of South Gate
Construction Industry Legislative Council
Culver City Chamber of Commerce
Fullerton Chamber of Commerce
Los Angeles Area Chamber of Commerce
Southwest California Legislative Council

Opposition

None

HISTORY:

Date	Action
2012	
Apr. 24	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13.
	Noes 0.) (April 24). Re-referred to Com. on APPR.
Apr. 17	Set for hearing April 24.
Apr. 12	Withdrawn from committee. Re-referred to Com. on G.O.
Apr. 11	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9.
	Noes O. Page 3120.) (April 11). Re-referred to Com. on APPR.
Apr. 9	From committee with author's amendments. Read second time and
	amended. Re-referred to Com. on GOV. & F.
Mar. 22	Set for hearing April 11.
Mar. 1	Referred to Coms. on GOV. & F. and G.O.
Feb. 23	From printer. May be acted upon on or after March 24.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To
	print.

Bill Analysis: SB 1185 as amended

Introduced by Senator Price

February 22, 2012

An act to amend Section 6253.3 of the Government Code, relating to public records add Part 6.01 (commencing with Section 12665) to Division 2 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1195, as amended, Price. California Public Records Act. Audits of pharmacy benefits.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. Existing law provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for specified benefits and requires contracts between plans or insurers and providers to contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism.

This bill would require a contract entered into between a pharmacy and a health insurer, health care service plan, or pharmacy benefit manager, as defined, for the provision of pharmacy services to beneficiaries of a health benefit plan, to include policies and procedures for any audits under the contract, and would impose specified requirements on those audits. Among other things, the bill would prohibit the entity conducting the audit from receiving payment on any basis tied to the amount claimed or recovered from the pharmacy and would require the entity to deliver a preliminary audit report to the

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pharmacy and to give the pharmacy an opportunity to respond to the report. The bill would require the entity to deliver a final audit report to the pharmacy and to establish a process for appealing the findings of that report, as specified. The bill would prohibit the entity from using extrapolation, as defined, in calculating penalties or amounts to be recouped from a pharmacy and would prohibit a pharmacy from being subject to recoupment of funds for a clerical or recordkeeping error. The bill would enact other related provisions.

The California Public Records Act requires state and local agencies to make public records available for inspection by the public, subject to specified criteria, and with specified exceptions. The act prohibits a state or local agency from allowing another party to control the disclosure of information otherwise subject to disclosure pursuant to the act.

This bill would make a technical, nonsubstantive change to this provision.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Part 6.01 (commencing with Section 12665) is 2 added to Division 2 of the Insurance Code, to read: 3

PART 6.01. AUDITS OF PHARMACY BENEFITS

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12665. For purposes of this article, the following definitions shall apply:

- (a) "Carrier" means a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106.
- (b) "Clerical or recordkeeping error" includes, but is not limited to, a typographical error, scrivener's error, or computer error in a required document or record.
- (c) "Extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.

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(d) "Health benefit plan" means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106, issued by a health insurer.

- (e) "Pharmacy" has the same meaning provided in Section 4037 of the Business and Professions Code.
- (f) "Pharmacy audit" means an audit, either onsite or remotely, of any records of a pharmacy conducted by or on behalf of a carrier or a pharmacy benefits manager, or a representative thereof, for prescription drugs that were dispensed by that pharmacy to beneficiaries of a health benefit plan pursuant to a contract with the health benefit plan or the issuer or administrator thereof.
- (g) "Pharmacy benefit manager" means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.
- 12665.1. (a) Nothing in this article shall apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other third-party payer has evidence or a significant suspicion that criminal wrongdoing, willful misrepresentation, or fraud has occurred.
- (b) Nothing in this article shall apply to an audit conducted by the California State Board of Pharmacy, the State Department of Health Care Services, or the State Department of Public Health.
- 12665.2. Notwithstanding any other provision of law, a contract that is issued, amended, or renewed on or after January 1, 2013, between a pharmacy and a carrier or a pharmacy benefit manager to provide pharmacy services to beneficiaries of a health benefit

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plan shall include policies and procedures for any audits performed under the contract. The policies and procedures shall be consistent with generally accepted auditing practices and shall comply with the provisions of this part.

- 12665.3. (a) An entity conducting a pharmacy audit shall not receive payment or any other consideration on any basis that is tied to the amount claimed or actual amount recovered from the pharmacy that is the subject of the audit.
- (b) An entity conducting a pharmacy audit shall not use extrapolation in calculating penalties or amounts to be recouped from a pharmacy. Any findings of overpayment or underpayment to a pharmacy shall be based solely on documented instances of overpayment or underpayment to the pharmacy and shall not be based on an estimate or projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
- (c) Any calculation of overpayment to a pharmacy determined pursuant to a pharmacy audit shall not include the portion of any payment that constitutes dispensing fees.
- (d) A pharmacy shall not be subject to recoupment of funds for a clerical or recordkeeping error, unless there is proof of intent to commit fraud or that the error resulted in actual financial harm to the pharmacy benefit manager, the carrier, or the beneficiary of a health benefit plan.
- 12665.4. (a) Except as otherwise prohibited by state or federal law, an entity conducting a pharmacy audit shall keep confidential any information collected during the course of the audit and shall not share any information with any person other than the carrier, pharmacy benefit manager, or third-party payer for which the audit is being performed. An entity conducting a pharmacy audit shall have access only to previous audit reports relating to a particular pharmacy conducted by or on behalf of the same entity. Nothing in this subdivision shall be construed to authorize access to information that is otherwise prohibited by law.
- (b) An entity that is not a carrier or pharmacy benefit manager and that is conducting a pharmacy audit on behalf of a carrier or pharmacy benefit manager shall, prior to conducting the audit, provide the pharmacy with an attestation that the entity and the carrier or pharmacy benefit manager have executed a business

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associate agreement or other agreement as required under state and federal privacy laws.

- (c) An entity conducting a pharmacy audit shall, prior to leaving a pharmacy at the end of an onsite portion of the audit, provide the pharmacist in charge with a complete list of records reviewed to allow the pharmacy to account for disclosures as required by state and federal privacy laws.
- 12665.5. (a) An entity conducting a pharmacy audit shall not initiate or schedule a pharmacy audit during the first five business days of any calendar month, unless it is expressly agreed to by the pharmacy being audited.
- (b) An entity conducting an onsite pharmacy audit shall provide the pharmacy at least one week's prior written notice before conducting an initial audit.
- 12665.6. (a) A pharmacy audit that involves clinical judgment shall be conducted by a pharmacist licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.
- (b) An entity conducting a pharmacy audit shall make all determinations regarding the legal validity of a prescription or other record consistent with determinations made pursuant to Article 4 (commencing with Section 4070) of Chapter 9 of Division 2 of the Business and Professions Code and shall accept as valid electronically stored images of prescriptions, electronically created annotations, and other related supporting documentation.
- (c) An entity conducting a pharmacy audit shall accept paper or electronic signature logs that indicate the delivery of pharmacy services as valid proof of receipt of those services by a health benefit plan beneficiary.
- 12665.7. The time period covered by a pharmacy audit shall not exceed a 24-month period beginning no more than 24 months prior to the initial date of the onsite portion of the audit, and the audit shall encompass only claims that were submitted to or adjudicated by the carrier or pharmacy benefit manager during that 24-month period.
- 12665.8. (a) (1) An entity conducting a pharmacy audit shall deliver a preliminary audit report to the pharmacy before issuing a final audit report. This preliminary report shall be issued no later than 60 days after conclusion of the audit.

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(2) A pharmacy shall be provided a time period of no less than 30 days following receipt of the preliminary audit report under paragraph (1) to respond to the findings in the report, including addressing any alleged mistakes or discrepancies and producing documentation to that effect.

- (3) A pharmacy may use the records of a health facility, physician and surgeon, or other authorized practitioner of the healing arts involving drugs, medicinal supplies, or medical devices written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a dangerous drug or device.
- (4) Prior to issuing a final audit report, an entity conducting a pharmacy audit shall take into consideration any response by the pharmacy to the preliminary audit report.
- (b) (1) An entity conducting a pharmacy audit shall deliver a final audit report to the pharmacy no later than 90 days after the conclusion of the audit or 30 days after receipt of a pharmacy's response to the preliminary audit report, as applicable.
- (2) An entity conducting a pharmacy audit shall establish a process for appealing the findings in a final audit report that complies with the following requirements:
- (A) A pharmacy shall be provided a time period of no less than 60 days following receipt of the final audit report to file an appeal with the entity identified in the appeal process.
- (B) A pharmacy may use the records of a hospital, physician and surgeon, or other authorized practitioner of the healing arts involving drugs, medicinal supplies, or medical devices written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a dangerous drug or device.
- (C) An entity conducting a pharmacy audit shall provide the pharmacy with a written determination of appeal issued by the entity identified in the appeal process, which shall be appended to the final audit report, and a copy of the determination shall be sent to the carrier, health benefit plan sponsor, or other third-party payer.
- (D) The appeals process may include a dispute resolution option as long as the pharmacy retains the right to file a written appeal and obtain a written determination pursuant to this subdivision.

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(c) An entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, shall not attempt to make chargebacks or seek recoupment from a pharmacy, or assess or collect penalties from a pharmacy, until the time period for filing an appeal to a final audit report has passed, or until the appeal process has been exhausted, whichever is later.

- (d) An entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, shall not charge interest during the audit or appeal period.
- (e) If, following final disposition of a pharmacy audit pursuant to this section, an entity conducting a pharmacy audit, a carrier, a health benefit plan sponsor, or other third-party payer, or any person acting on behalf of those entities, finds that an audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion thereof without the necessity of any further proceedings and shall return any moneys recouped as a result of the lack of substantiation, as applicable.

SECTION 1. Section 6253.3 of the Government Code is amended to read:

6253.3. A state or local agency may not allow another party to control the disclosure of information otherwise subject to disclosure pursuant to this chapter.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: SB 1195 VERSION: As Amended March 26, 2012

AUTHOR: Price SPONSOR: California Pharmacists Association

RECOMMENDED BOARD POSITION: None, committee noted that this area is not regulated by

the board.

SUBJECT: Audits of pharmacy benefits

AFFECTED SECTIONS: Add Part 6.01 (commencing with Section 12665) to Division 2 of the

Insurance Code

CURRENT STATUS: Senate Health Committee hearing scheduled for April 24, 2012

EXISTING LAW:

1. Provides for the regulation of pharmacy services through the California State Board of Pharmacy.

- 2. Provides for the regulation of health care services plans by the Department of Managed Health Care.
- 3. Provides for the regulation of health insurers by the Department of Insurance.

THIS BILL WOULD:

- Specify that an audit conducted by or on behalf of a pharmacy benefit manager shall be consistent with generally accepted auditing practices and in conformance with the provisions specified.
- 2. Prohibit an entity performing an audit from receiving payment or other considerations on any basis that is tied to an amount claimed or actual amount recovered from a pharmacy that is subject to an audit.
- 3. Specify how calculations can be used to determine overpayment and underpayment of claims.
- 4. Provide the parameters around confidentiality, contract agreements, clerical and recordkeeping errors, notice requirements and timeframes.
- 5. Set forth an appeal process.

AUTHOR'S INTENT:

This legislation will follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers, or "PBMs."

COMMENTS:

The bill was amended April 25, 2012, but the amendments are not yet in print. Board staff will bring updated information to the meeting it available.

SB 1195 Version: As Amended April 25, 2012

Pharmacy Benefit Managers are currently not regulated. Although the board does not have jurisdiction over the auditing of claims for reimbursement, board staff receive complaints on a somewhat routine basis from licensees complaining about the perceived unjust auditing practice of an auditing company receiving payment based on the number of claims rejected. This proposal would appear to address this issue.

FISCAL IMPACT:

Board staff does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date	Action
2012	
Apr. 10	Set for hearing April 24.
Apr. 9	Set, first hearing. Hearing canceled at the request of author.
Apr. 5	Set for hearing April 18.
Mar. 29	Re-referred to Coms. on HEALTH and RLS.
Mar. 26	From committee with author's amendments. Read second time and
	amended. Re-referred to Com. on RLS.
Mar. 1	Referred to Com. on RLS.
Feb. 23	From printer. May be acted upon on or after March 24.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Bill Analysis: SB 1195 as amended

Introduced by Senator Alquist

February 23, 2012

An act to amend Section 56.36 of the Civil Code, relating to medical records.

LEGISLATIVE COUNSEL'S DIGEST

SB 1250, as introduced, Alquist. Medical records: confidentiality.

The Confidentiality of Medical Information Act requires that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records do so in a manner that preserves the confidentiality of the information contained in the records, and provides that negligence in conducting these activities may result in damages or an administrative fine or civil penalty, as specified.

This bill would provide that negligence in conducting these activities may result in the defendant being required to provide each person who is the subject of the medical records with access to a credit monitoring and reporting service for one year.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 56.36 of the Civil Code is amended to 2 read:
- 3 56.36. (a) Any violation of the provisions of this part that
- 4 results in economic loss or personal injury to a patient is punishable
- 5 as a misdemeanor.

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(b) In addition to any other remedies available at law, any individual may bring an action against any person or entity who that has negligently released confidential information or records concerning him or her in violation of this part, for access, at the defendant's expense, to a nationally recognized credit monitoring and reporting service for one year from the date of release of any medical information and either or both of the following:

- (1) Nominal damages of one thousand dollars (\$1,000). In order to recover under this paragraph, it shall not be necessary that the plaintiff suffered or was threatened with actual damages.
- (2) The amount of actual damages, if any, sustained by the patient.
- (c) (1) In addition, any person or entity that negligently discloses medical information in violation of the provisions of this part shall also be liable, irrespective of the amount of damages suffered by the patient as a result of that violation, for an administrative fine or civil penalty not to exceed two thousand five hundred dollars (\$2,500) per violation.
- (2) (A) Any person or entity, other than a licensed health care professional, who knowingly and willfully obtains, discloses, or uses medical information in violation of this part shall be liable for an administrative fine or civil penalty not to exceed twenty-five thousand dollars (\$25,000) per violation.
- (B) Any licensed health care professional, who knowingly and willfully obtains, discloses, or uses medical information in violation of this part shall be liable on a first violation, for an administrative fine or civil penalty not to exceed two thousand five hundred dollars (\$2,500) per violation, or on a second violation for an administrative fine or civil penalty not to exceed ten thousand dollars (\$10,000) per violation, or on a third and subsequent violation for an administrative fine or civil penalty not to exceed twenty-five thousand dollars (\$25,000) per violation. Nothing in this subdivision shall be construed to limit the liability of a health care service plan, a contractor, or a provider of health care that is not a licensed health care professional for any violation of this part.
- (3) (A) Any person or entity, other than a licensed health care professional, who knowingly or willfully obtains or uses medical information in violation of this part for the purpose of financial gain shall be liable for an administrative fine or civil penalty not

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to exceed two hundred fifty thousand dollars (\$250,000) per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the violation.

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- (B) Any licensed health care professional, who knowingly and willfully obtains, discloses, or uses medical information in violation of this part for financial gain shall be liable on a first violation, for an administrative fine or civil penalty not to exceed five thousand dollars (\$5,000) per violation, or on a second violation for an administrative fine or civil penalty not to exceed twenty-five thousand dollars (\$25,000) per violation, or on a third and subsequent violation for an administrative fine or civil penalty not to exceed two hundred fifty thousand dollars (\$250,000) per violation and shall also be subject to disgorgement of any proceeds or other consideration obtained as a result of the violation. Nothing in this subdivision shall be construed to limit the liability of a health care service plan, a contractor, or a provider of health care that is not a licensed health care professional for any violation of this part.
- (4) Nothing in this subdivision shall be construed as authorizing an administrative fine or civil penalty under both paragraphs (2) and (3) for the same violation.
- (5) Any person or entity—who that is not permitted to receive medical information pursuant to this part and who knowingly and willfully obtains, discloses, or uses medical information without written authorization from the patient shall be liable for a civil penalty not to exceed two hundred fifty thousand dollars (\$250,000) per violation.
- (d) In assessing the amount of an administrative fine or civil penalty pursuant to subdivision (c), the Office of Health Information Integrity, licensing agency, or certifying board or court shall consider any one or more of the relevant circumstances presented by any of the parties to the case including, but not limited to, the following:
- (1) Whether the defendant has made a reasonable, good faith attempt to comply with this part.
 - (2) The nature and seriousness of the misconduct.
- 37 (3) The harm to the patient, enrollee, or subscriber.
 - (4) The number of violations.
- 39 (5) The persistence of the misconduct.
- 40 (6) The length of time over which the misconduct occurred.

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- 1 (7) The willfulness of the defendant's misconduct.
 - (8) The defendant's assets, liabilities, and net worth.
 - (e) (1) The civil penalty pursuant to subdivision (c) shall be assessed and recovered in a civil action brought in the name of the people of the State of California in any court of competent jurisdiction by any of the following:
 - (A) The Attorney General.
 - (B) Any district attorney.
 - (C) Any county counsel authorized by agreement with the district attorney in actions involving violation of a county ordinance.
 - (D) Any city attorney of a city.
 - (E) Any city attorney of a city and county having a population in excess of 750,000, with the consent of the district attorney.
 - (F) A city prosecutor in any city having a full-time city prosecutor or, with the consent of the district attorney, by a city attorney in any city and county.
 - (G) The Director of the Office of Health Information Integrity may recommend that any person described in subparagraphs (A) to (F), inclusive, bring a civil action under this section.
 - (2) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half to the General Fund. If the action is brought by a district attorney or county counsel, the penalty collected shall be paid to the treasurer of the county in which the judgment was entered. Except as provided in paragraph (3), if the action is brought by a city attorney or city prosecutor, one-half of the penalty collected shall be paid to the treasurer of the city in which the judgment was entered and one-half to the treasurer of the county in which the judgment was entered.
 - (3) If the action is brought by a city attorney of a city and county, the entire amount of the penalty collected shall be paid to the treasurer of the city and county in which the judgment was entered.
 - (4) Nothing in this section shall be construed as authorizing both an administrative fine and civil penalty for the same violation.
 - (5) Imposition of a fine or penalty provided for in this section shall not preclude imposition of any other sanctions or remedies authorized by law.

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(6) Administrative fines or penalties issued pursuant to Section 1280.15 of the Health and Safety Code shall offset any other administrative fine or civil penalty imposed under this section for the same violation.

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- (f) For purposes of this section, "knowing" and "willful" shall have the same meanings as in Section 7 of the Penal Code.
- (g) No person who discloses protected medical information in accordance with the provisions of this part shall be subject to the penalty provisions of this part.
- 10 (h) Paragraph (6) of subdivision (e) shall only become operative 11 if Senate Bill 541 of the 2007–08 Regular Session is enacted and 12 becomes effective on or before January 1, 2009.

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: SB 1250 VERSION: As Introduced February 23, 2012

AUTHOR: Alquist SPONSOR: Author

RECOMMENDED BOARD POSITION: None

SUBJECT: Medical Records: Confidentiality

AFFECTED SECTIONS: Act to amend Section 56.36 of the Civil Code

CURRENT STATUS: Referred to Senate Judiciary Committee

EXISTING LAW:

1. Establishes the Confidentiality of Medical Information Act that specifies the confidentiality of information maintained medical records by health care providers, health coverage plans, pharmaceutical companies and other contractors as specified.

2. Established monetary penalties for individuals and entities that violation this act.

THIS BILL WOULD:

Specify that in addition to other legal remedies, a defendant may be required to pay for credit monitoring and reporting services for one year from the unauthorized release of medical information.

COMMENTS:

Board staff was unable to speak with the author's office. Additional information will be provided during the committee meeting if available.

FISCAL IMPACT:

Board staff does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date Action

2012

Mar. 8 Referred to Com. on JUD.

Feb. 24 From printer. May be acted upon on or after March 25.

Feb. 23 Introduced. Read first time. To Com. on RLS. for assignment. To

print.

Introduced by Assembly Member Torres

February 24, 2012

An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2342, as introduced, Torres. Controlled substances.

Existing law classifies certain controlled substances into designated schedules, and prohibits, except as specified, a controlled substance classified in Schedule II, III, IV, or V from being dispensed without a prescription, as specified.

Existing law requires the Department of Justice, contingent upon the availability of adequate funds from various funds related to health care, to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

This bill would make a technical, nonsubstantive change to the provision requiring the Department of Justice to maintain CURES for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances, as described above.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

AB 2342 — 2 —

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The people of the State of California do enact as follows:

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

- 11165. (a) To In order to assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
- (b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.
- (c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer

-3- AB 2342

1 review, statistical, or research purposes, provided that patient 2 information, including any information that may identify the 3 patient, is not compromised. Further, data disclosed to any 4 individual or agency as described in this subdivision shall not be 5 disclosed, sold, or transferred to any third party.

- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:
- (1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, and federal controlled substance registration number.
- (4) NDC (National Drug Code) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
 - (6) ICD-9 (diagnosis code), if available.
- 29 (7) Number of refills ordered.

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- 30 (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- 32 (9) Date of origin of the prescription.
- 33 (10) Date of dispensing of the prescription.
- 34 (e) This section shall become operative on January 1, 2005.

Introduced by Assembly Member Logue

February 16, 2012

An act to amend Section 1374.13 of the Health and Safety Code, relating to health care service plans.

LEGISLATIVE COUNSEL'S DIGEST

AB 1733, as introduced, Logue. Health care service plans: telehealth. Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law prohibits a health care service plan from requiring in-person contact between a health care provider and a patient before payment is made for covered services appropriately provided through telehealth, as specified. Existing law specifies that this requirement applies to certain Medi-Cal managed care plans, including county organized health systems and entities contracting with the department to provide services pursuant to 2-plan models and geographic managed care.

This bill would specify that the prohibition on requiring in-person contact also applies to other health care service plan contracts with the State Department of Health Care Services for services under the Medi-Cal program publicly supported programs other than Medi-Cal, and for services pursuant to the Program of All-Inclusive Care for the Elderly. By expanding the scope of a crime, the bill would impose a state-mandated local program.

AB 1733 -2-

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- SECTION 1. Section 1374.13 of the Health and Safety Code is amended to read:
- 1374.13. (a) For the purposes of this section, the definitions in subdivision (a) of Section 2290.5 of the Business and Professions Code shall apply.
 - (b) It is the intent of the Legislature to recognize the practice of telehealth as a legitimate means by which an individual may receive health care services from a health care provider without in-person contact with the health care provider.
 - (c) No health care service plan shall require that in-person contact occur between a health care provider and a patient before payment is made for the covered services appropriately provided through telehealth, subject to the terms and conditions of the contract entered into between the enrollee or subscriber and the health care service plan, and between the health care service plan and its participating providers or provider groups.
 - (d) No health care service plan shall limit the type of setting where services are provided for the patient or by the health care provider before payment is made for the covered services appropriately provided through telehealth, subject to the terms and conditions of the contract entered into between the enrollee or subscriber and the health care service plan, and between the health care service plan and its participating providers or provider groups.
 - (e) The requirements of this subdivision shall also be operative for health care service plan contracts with the department pursuant to Article 2.7 (commencing with Section 14087.3), Article 2.8 (commencing with Section 14087.5), Article 2.81 (commencing with Section 14087.96), or Article 2.91 (commencing with Section 14089) of Chapter 7, or section shall also apply to health care service plan contracts with the State Department of Health Care

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Services pursuant to Chapter 7 (commencing with Section 14000),
 Chapter 8 (commencing with Section 14200), or Chapter 8.75
 (commencing with Section 14591) of, Part 3 of Division 9 of the
 Welfare and Institutions Code.

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- (f) Notwithstanding any other provision, this section shall not be interpreted to authorize a health care service plan to require the use of telehealth when the health care provider has determined that it is not appropriate.
- 9 SEC. 2. No reimbursement is required by this act pursuant to 10 Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school 11 district will be incurred because this act creates a new crime or 12 13 infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of 14 15 the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California 16 17 Constitution.

STATE SERVICE SERVICE

DAN LOGUE

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AB 1733 Telehealth Advancement Act Follow Up

Purpose

This bill would remove barriers in current law and update to current practice the use of telehealth in the delivery of health care, by furthering the application of AB 415 (Logue, 2011) to *all* remaining health care service plan contracts with the Department of Health Care Services. This consists of the Program of All-Inclusive Care for the Elderly (PACE), the SCAN Health Plan, and the AIDS Healthcare Foundation.

Background

Last year the California Legislature led the nation by passing landmark legislation in "The Telehealth Advancement Act of 2011" (AB 415, Logue). AB 415 removed barriers in California law to the use of telehealth in the delivery of health care, while maintaining the original legislative intent of California's Telemedicine Development Act of 1996. It updated the law to apply the new definition of telehealth to all licensed health professionals, removed duplicative procedures, and recognized advances in health care technology. Telehealth has the potential to reduce costs, increase access and improve quality of care, especially in underserved areas of the state where it is difficult to get specialized care.

California was the first state to pass legislation (the Telemedicine Development Act of 1996) that, among other things, established telemedicine as a legitimate means of receiving health care services, and provided parameters for reimbursement in both private and public health coverage plans. With the Telehealth Advancement Act of 2011, California regained its place of leadership on the national health care stage.

Support

California State Rural Health Association (sponsor) California Association of Physician Groups

Opposition

None at this time.

(Updated February 17, 2012)

CALIFORNIA STATE BOARD OF PHARMACY BILL ANALYSIS



BILL NUMBER: AB 1733 VERSION: As Amended April 16, 2012

AUTHOR: Logue SPONSOR: California State Rural Health Association

RECOMMENDED BOARD POSITION: None

SUBJECT: Telehealth

AFFECTED SECTIONS: Amend Section 1374.13 of the Health and Safety Code and add Section

14594 to the Welfare and Institutions Code

CURRENT STATUS: Assembly Health Committee hearing scheduled for April 24, 2012

EXISTING LAW:

1. Establishes the provisions for telehealth.

2. Prohibits a health care service plan from requiring in-person contact between a health care professional and a patient for purposes of receiving payment.

3. Defines the health care plans affected by this prohibition.

THIS BILL WOULD:

 Specify that the mandated in-person contact prohibition would also apply to health care service plan contracts with the Department of Health Care Services for services provided by the Medi-Cal program, other publicly support programs as well as to organizations implementing the California Program of All-Inclusive Care for the Elderly (PACE).

AUTHOR'S INTENT:

According to a fact sheet provided by the author's office, "This bill would remove barriers in current law and update to current practice the use of telehealth in the delivery of health care, by expanding the application of AB 415 (Logue, 2011) to all remaining contracts that health care service plans and other entities have with the Department of Health Care Services (DHCS). AB 415 effectively applied to all health care service plans in California, but failed to specifically reference two health care service plans that contract with DHCS – the SCAN Health Plan and the AIDS Healthcare Foundation. As well, AB 415 did not apply to entities contracting with DHCS under the Program of All-Inclusive Care for the Elderly (PACE)."

FISCAL IMPACT:

Board staff does not anticipate any significant impact. Any minor fiscal impact could be absorbed within existing resources.

AB 1733 Version: As Amended April 16, 2012

PREVIOUS LEGISLATION:

AB 415 (Logue, Chapter 547, Statutes of 2011) amended the definitions used to implement existing telehealth provisions.

SUPPORT/OPPOSITION:

Support

Aging Services of California
AIDS Healthcare Foundation
Association of California Healthcare Districts
California Academy of Physician Assistants
California Center for Rural Policy
California Healthcare Institute
California Primary Care Association
California Psychological Association
California State Rural Health Association
Several individuals

Opposition

None

HISTORY:

Date 2012	Action
Apr. 25	From committee: Do pass as amended and re-refer to Com. on APPR. with recommendation: to consent calendar. (Ayes 19. Noes 0.) (April 24).
Apr. 17	Re-referred to Com. on HEALTH.
Apr. 16	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 27	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 1	Referred to Com. on HEALTH.
Feb. 17	From printer. May be heard in committee March 18.
Feb. 16	Read first time. To print.

Bill Analysis: AB 1733 as amended Page 2

Introduced by Assembly Member Hill

(Coauthor: Senator Correa)

February 24, 2012

An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 2570, as introduced, Hill. Licensees: settlement agreements.

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct are not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity or person acting as an authorized agent of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil

2 **AB 2570**

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action to pay additional moneys to the benefit of any plaintiff in the civil action.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 143.5 is added to the Business and 2 Professions Code, to read:

- 143.5. (a) No licensee who is regulated by a board, bureau, or program within the Department of Consumer Affairs, nor an entity or person acting as an authorized agent of a licensee, shall include or permit to be included a provision in an agreement to settle a civil dispute, whether the agreement is made before or after the commencement of a civil action, that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A provision of that nature is void as against public policy, and any licensee who includes or permits to be included a provision of that nature in a settlement agreement is subject to disciplinary action by the board, bureau, or program.
- (b) Any board, bureau, or program within the Department of Consumer Affairs that takes disciplinary action against a licensee or licensees based on a complaint or report that has also been the subject of a civil action and that has been settled for monetary damages providing for full and final satisfaction of the parties may not require its licensee or licensees to pay any additional sums to the benefit of any plaintiff in the civil action.
- (c) As used in this section, "board" shall have the same meaning as defined in Section 22, and "licensee" means a person who has been granted a license, as that term is defined in Section 23.7.